EPA Jacket 2382-192



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

FEB 2 1 2013

2382-192

Term of Issuance:

Conditional

EFFITIXTM PLUS Topical Solution for Dogs

Name and Address of Registrant (include ZIP Code):

Virbac Animal Health, Inc. P.O Box 162059 Fort Worth, TX 76161

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered//reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you:

- 1. Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under section 4 of FIFRA.
- 2. Submit within 12 months of the date of issuance of this Registration Notice, acceptable guideline studies for Storage Stability study (OPPTS GLN: 830.6317) and Corrosion Characteristics study (OPTS GLN: 830.6320) for this product.
- 3. Change the product registration number to "EPA Reg. No. 2382-192" (continued on page 2)

Signature of Approving Official:	Date:
See page 2	FEB 2 1 2013
Richard Gebken, Product Manager (10) Insecticide Branch, Registration Division (7505P)	2010

EPA Fonn 8570-6

Conditions of acceptance

- 1. This registration is now time-limited and expires two years from the date of this letter.
- 2. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning April 1, 2013.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlon Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify) Breed: (as reported by pet owner)

Age: months or years Sex: M, F, or neutered Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely

Richard Gebken

Product Manager 10,

Insecticide Branch

Registration Division (7505P)

Enclosure: Label Stamped "with Comments"

Under the Federal Insequeide. Fungicide, and Rodenticide Act. as amended, for the pesticide registered under EPA Reg. No.

Virbac's Master Label

Date 21 February 2013 Version US-20 EPA Reg. No. 2382-xxx Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIXTM PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 5 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil.	6.0%
Permethin*	44.8%
Pyriproxyten	
OTHER INGREDIENTS:	47.4%
TOTAL;	100.0%
* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans	

KEEP OUT OF REACH OF CHILDREN CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS -- IF INGESTEO BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINAR/AN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

	FIRST AIO
IF SW ALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Oo not induce vomiting unless told to do so by a poison control center or doctor. Qo not give anything to an unconscious person.
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for t5-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labelling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR OOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON OOGS ONLY, OO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Oo not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Oo not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

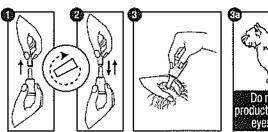
Oo not apply more often than once a [per[month [every 30 days).

For use on OOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use

APPLICATION DIRECTIONS

- Remove one applicator from packaging. Hold applicator upright and remove cap.
- Invert cap and place other end back onto applicator tip.
 Push cap down to break seal.
- Remove cap prior to treatment application.
- Part dog's hair until skin is visible.
 - Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or otder weighing 5 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIXTM Plus Topical Solution for Dogs is not applied superficially on dog's hair.









Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and tice infestations can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIXTM Plus Topical Solution for Dogs.

Fteas: EFFITtX^{IM} Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for Jup to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAO), or if reinfestation is likely

Ticks: EFFITIXTM Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed

Lice: EFFITIXTM Plus Topical Solution for Oogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIXTM Plus Topical Solution for Dogs aids in [the] control of [satcoptic mange]/[mite infestations that may cause sarcoptic mange).

Biting files and Mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs [prevents blood feeding by[[and] [repels] biting files and mosquitoes for up to 4 weeks [a [one) month). Kills mosquitoes for up to four weeks (a [one) month).

Notes; Wait at least 30 days before re-application of EFFITIXTM Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable, Do not reuse or refill this container. Offer for recycling, if available. If partially fitled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX[™] Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 5 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs t1 to 22.9 lbs (0.034 ft oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 ft oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 ft oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 ft oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.017 ft oz, (0.034 ft oz, 0.068 ft oz, 0.135 ft oz, 0.203 ft oz) (of solution).

[Detachable] catendar [monthly application] reminder stickers (with illustration of dog or puppy]

Back Panet (single presentation on side panel) EPA Reg. No. 2382-xxx EPA Est. No. 2382-FRA-1

VIRBAC AH, INC. PO BOX 162059 FORT WORTH TX 76161 1-800-338-3659

Made in France EFFITIX[™] is a trademark of Virbac S.A. Questions or comments 7 Call: 1-800-338-3659.

EPA Reg. No. 2382-xxx page 3 of 7 - Pending Master label Submitted February 21, 2013

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application. See package insert for directions for use and storage and disposal. See package insert for frequency of application and storage and disposal. Open resealable label for directions for use. Open resealable label for directions for use and storage and disposal. See back panel for additional precautionary statements. See package insert(s) for frequency of application. See enclosed insert(s) for directions for use and storage and disposal. See enclosed insert(s) for directions for use. Lift here to open (LIFT HERE TO OPEN). For Use on Dogs ONLY. Use ONLY on dogs. See inside flap for directions for use.

Text for Foil of Blister package

Virbac

EFFITIX™ Plus Topical Solution For Dogs

Only for use on dogs (5 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz ,0.034 fl oz,0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 5.0 mL)

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac EFFITIX™ Plus
Topical Solution For Dogs
Only for use on dogs
(51o 10.9 lbs, 11 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/
(0.017 ft oz, 0.034 ft oz, 0.068 ft oz, 0.135 ft oz, 0.203 ft oz) (/ (0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0mL))
Contains fipronil (6.0%), permethón (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions OO NOT USE ON CATS EPA Reg. No. 2382-xxx CAT PROHIBITION ICON

MARKETING CLAIMS

(Multiple infestations)

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFITIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea tarvae, [biting, chewing] lice, aids in the control of sarcoptic mites, and repels] and inhibits
 blood feeding by biting files and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, (biting, chewing) lice, aids in the control of mites that may cause sarcoptic mange, and repels Jand inhibits blood feeding by biting fles and mosquitoes.
 For easy and convenient application, EFFITIXTM Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8]
- For easy and convenient application, EFFITIX[™] Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 5 to 10.9 lbs [0.17 fl oz](0.5 mL], small dogs 11 to 22.9 lbs [0.034 fl oz] 1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz] (2.0 mL], large dogs 45-88.9 lbs (0.135 fl oz] (4.0 mL], and extra large dogs 89-132 lbs [0.203 fl oz] 16.0 mL1.
- J6.0 mL).
 EFFITIXTM Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel (against) biting flies, and repel and fill mescriptoes.
- · Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- · Repels fleas, ticks, biting flies and mosquitoes
- · Kills and repels ticks
- · For the control and prevention of flea, flea egg, flea pupae, flea larvae, Jand lice] infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick [biting and chewing] lice infestations, can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIXTM Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and
- Long tasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIXTM Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Heips to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestalions
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spolted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosqvitoes.

(Fleas]

- Fleas: EFFITIXTM Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermalitis [FAD], or if reinfestation is
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution
- Prevents all flea stages (adult fleas, flea eggs, flea pypae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethan to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen (IGR)* to break [the[flea life cycle *insect growth regulator
- Kills fleas (within 6 hours) that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas (within 6 hours) that may transmit the following diseases: bartonellosis, (tularaemia) [and tapeworm infestations]
- Kills fleas [wilhin 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [Dipylidium caninum]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills [adult] fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] (or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] (annoying] (flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermatilis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD)
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermalitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and pupples 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and pupples 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermalitis (FAD), or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis, (tularemia[[and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents (Stops) re-infestations by killing adult fleas (before they lay eggs)
- Treatment with EFFITIXTM Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention[[protection] year-round

[Ticks]

- Ticks: EFFITIXTM Plus Topical Solution for Dogs can kill ticks for [up to] at least jone] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis)
- Kills ticks including Deer ticks (that may transmit Lyme disease and anaplasmosis), American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis[for up to one month [4 weeks[
- Kills ticks including Deer ticks (that may transmit Lyme disease and anaplasmosis), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks [that may transmit ehrlichiosis] for up to one month]4 weeks].
- Kills Brown dog ticks [Rhipicephalus spp], American dog ticks [Dermacentor variabilis], Deer ticks [fxodes spp] and Lone Star ticks [Ambfyomma americanum] for up to one month [4 weeks].
- Kills Lone Starticks (Amblyomma americanum) for 4 weeks) for up to one month[.
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days]four weeks] [a [one] month)
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs [prevents blood feeding by] [and] (repels) biting flies and mosquitoes for (up to) 4 weeks [a (one) month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits] blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] [Kills and repels]] mosquitoes
- Repets biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits []annoying]]bothersome [(nuisance]) biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos (Culex spp, Dohferotalus spp, Aedes spp) which may vector heartworm (Dirofilaria immilis) for one month

)Lice and Mites]

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a {one} month. Apply monthly where lice control is consistently needed.

 Mites: [EFFITIXTM Plus Topical Solution for Dogs] aids in [the] control of mites that may cause sarcoptic mange.

 Mites: [EFFITIXTM Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites

- EFFITIX^{TN} Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIXTM Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
-) Also) Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [] biting] [chewing]) lice
- For control and prevention of [[biting] [chewing]] lice [infestations]
- Stops existing ([biting] (chewing)] lice infestations
- Prevents and controls ((biting) (chewing)[lice (infestations)
- Provides effective control of [[biting]]chewing][lice [infestations]
- Kills [[biting] [chewing]] lice and prevents further infestations
- For control and prevention of)infestation ((with) (biting)]chewing)] lice

(Others)

- 1 (3, 6, 36) applicator(s) (tube(s)) 0.5 mL (t.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- 1 (3, 6, 36) applicator(s) [tube(st) 0.017 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.0 f7 fl oz [0.5 mL], [0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL), 0.203 fl oz (6.0 mL))
- 1 [3, 6, 36) applicator(s) [tube)s]] (each) containing 0.017 fl oz [0.5mL] (0.034 fl oz] t.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL])
- t (3, 6, 36) applicator(s) (tube(s))
- t (3, 6, 36) monthly dose(s) (application(s))
- t (3, 6, 36) applicator(s) [tube(s)] 1 (3, 6, 36) month(ly) dose(s) (application(s)
- DO NOT USE DN CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 5 to 10.9 lbs, weighing 1t to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application [applications]
- Remains effective for a [one] month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a [one] month
- Convenient topical treatment for dogs

- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-linfestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply] spot-on [topical] application
- Fragrance Jodor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]
 EFFITIXTM Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight
- Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month[[for one month] [for up to four weeks][
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of touse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

BARCODE No.: 407438; DECISION No.: 468313 FILE SYMBOL No.: 2382-ROE;

Men 02-08-13

PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs; ;

PC Code(s): 129121, 129032 & 109701; Action Code: R310; FOOD Use: No

DATE: January 25, 2013

SUBJECT: Product Name: Effipro Plus Topical Solution for Dogs

FROM: Akiva Abramovitch, Ph.D.

Technical Review Branch / RD (7505P)

THROUGH: Shyam Mathur, Ph.D.

Product Chemistry Team Leader Technical Review Branch/RD (7505P)

TO: Driss Benmehend/Richard Gebken, PM 10

Insecticide Branch/RD (7505C)

Company Name: Virbac

Formulation Type: Spot-On Solution

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 488963-01 through -08). The CSF of the basic formulation (dated 07/15/2012) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF dated October 15, 2012 and Alternate CSF #1 dated July 12, 2012.

SUMMARY OF FINDINGS:

- 1. Name of Active Ingredient: Fipronil (6.0%), permethrin (44.8%) and Pyriproxyfen (1.8%).
- 2. Has the registrant claimed substantial similarity to a registered product?
 - [] Yes; [X] No; if yes give the registration number of the cited product.
- 3. All the source materials for the active ingredients are derived from the registered sources: [X] Yes; [] No.

BARCODE No.: 407438; DECISION No.: 468313 FILE SYMBOL No.: 2382-ROE PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs; ;
PC Code(s): 129121, 129032 & 109701; Action Code: R310; FOOD Use: No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: [X] Yes; [] No.
5. Confidential Statement of Formula(s):
[X] Basic CSF Dated: July 12, 2012; [X] Alternate CSF #1 Dated: July 15, 2012
6. Product label
 a. Ingredient statement: Nominal concentration of Al listed on CSF(s) concur with product labe (PR Notice 91-2).
[X] Yes, if not, explain below:
Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)' [X] Yes; [] No; if not, explain below:
Metallic equivalent: [] Yes [X] NA; Soluble arsenic: [] Yes [X] NA Isomeric ratios: [] Yes [X] NA Acid equivalent: [] Yes [X] NA; {name} acid equivalent = xx %
b. Health related sub statements: Product contains?
Petroleum distillate at > 10%: [] Yes [X] No [] NA Methanol at > 4%: [] Yes [X] No [] NA Sodium nitrate/Sodium nitrite [] Yes [X] No [] NA
 c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown? [] Yes [X] No
ls the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)? [] Yes, [] No, [X] NA, if not, explain below:
d. Label requires an additional Storage and Disposal statement: [] Yes [X] No

BARCODE No.: 407438; DECISION No.: 468313 FILE SYMBOL No.: 2382-ROE;

PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs; ;

PC Code(s): 129121, 129032 & 109701; Aetion Code: R310; FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline	Study Title		Data submitted		TRB's Assessment		
No.			Yes	No	of Data	MRID Nos.	
	Product Idea	ntity &					
830.1550	Composition	n	X		A	488963-01	
830.1600	Description to produce t	of materials used he product	X		A	488963-01	
830.1650	Description of formulation process		X		A	488963-01	
830.1670	Discussion on the formation of impurities		X		A	488963-01	
830.1700	Preliminary	analysis	Х		A	488963-02	
	Certified	Standard certified Limits	х		A		
	limits (158.350)	Proposed Limits			N A		
830.1750		Justification for wider limits			NA	488963-01	
830.1800	Enforcement method	t analytical	X		A (HPLC method)	488963-02	

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Clear yellow oderless liquid	A	488963-03
830.6315	Flammability	97.3°C flashpoint	A	488963-05

BARCODE No.: 407438; DECISION No.: 468313 FILE SYMBOL No.: 2382-ROE;

PRODUCT NAME: Effitix TM Plus Topical Solution for Dogs;;

PC Code(s): 129121, 129032 & 109701; Action Code: R310; FOOD Use: No NA, not considered to be Explodability potentially explosive W 830.6316 488963-07 830.7000 pΗ 6.32 1% solution at 22 C Α Density (units) Α 488963-08 830,7300 1.1163 g/cm³

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress, U = Upgradeable

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

- 1. The proposed CSF for the basic formulation dated July 12, 2012 and the Alternate CSF #1 dated July 15, 2012 are acceptable
- 2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.
- 3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) are acceptable.
- 4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies were not submitted and will be conducted. These physical/chemical properties are required and it is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
- 5. The proposed label was screened as it pertains to the product chemistry requirements. Review of the proposed label and uses are the purview of the RM team.

DATA PACKAGE BEAN SHEET

Date: 10-Dec-2012 Page t of 3

Decision #: 468313

DP #: (407438)

PRIA

Parent DP #:

Submission #: 921393

E-Sub #: 3261

Registration Information * * * Registration: 2382-ROE - EFFITIX TM PLUS Topical Solution for Dogs Company: 2382 - VIRBAC AH, INC. Risk Manager: RM 10 - Richard Gebken - (703) 305-670 t Room# PY t S-7237 Risk Manager Reviewer: Driss Benmhend DBENMHEN Sent Date: PRIA Due Date: 23-Feb-2013 Edited Due Date: Type of Registration: Product Registration - Section 3 Action Desc: (R310) NEW PRODUCT; NDN-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIS? Ingredients: See page 3 * * * Data Package Information * * * Expedite: Yes No Date Sent: 10-Dec-2012 Due Back: DP Ingredient: See page 3 DP Title: Initial application for a new spot-on product CSF Included: Yes No Parent DP #: Assigned To Date Out Organization: RD / TRB Last Possible Science Due Date: 24-Jan-2013 Team Name: Science Due Date: Reviewer Name: Sub Data Package Due Date: Contractor Name: Studies Sent for Review * * * Printed on Page 2 Additional Data Package for this Decision * * *

Can be printed on its own page

* * Data Package Instructions * * *

Virbac has requested the registration of this fipronil/permethrin/nylar product. I'm requesting an expedited review, as the jacket with 15 volumes of data has been missing since initially received.

Attached is the 8570-t Transmittal lelter Basic CSF and 1 Alternate CSF. Data Matrix Formulator's exemption statement

Copy ot proposed label.

This is the product chemistry package.

All of the studies referenced are in documentum, so there are no hard copies to send with this BEAN.

* * * Studies Sent for Review * * *

Decision#: (468313)

DP#: (407438)	* * * Studies Sent for Review * '		Decision#: (468313)	
MRID MRID Status	Citation Reference	Guideline	86-5 Status	
48896301	Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/16/1/OCR, Unpublished study prepared by Virbac. 54p.	830.1550/Product Identity and composition	Pass (14-Aug-2012)	
4889630 t	Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/104/16/1/OCR. Unpublished study prepared by Virbac. 54p.	830.1600/Description of materials used to produce the product	Pass (14-Aug-2012)	
48896301	Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/t04/t6/1/OCR. Unpublished study prepared by Virbac. 54p.	830.1620/Description of production process	Pass (14-Aug-2012)	
48896301	Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/104/16/1/OCR. Unpublished study prepared by Virbac. 54p.	830.1650/Description of formulation process	Pass (14-Aug-2012)	
48896301	Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/104/t6/t/OCR. Unpublished study prepared by Virbac. 54p.	830.1670/Discussion of formation of impunties	Pass (14-Aug-2012)	
48896301	Villard, I. (2012) Product Specific Chemistry For Effitix Plus Topical Solution for Dogs. Project Number: VIRBAC/104/16/t/OCR. Unpublished study prepared by Virbac. 54p.	830.1750/Certified limits	Pass (14-Aug-2012)	
48896302	Schoop, T. (2012) t04.16: Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxyfen in Five Balches by Validated Methods: Final Report. Project Number: D42226/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 79p.			
48896302	Schoop, T. (2012) t04.16: Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxyfen in Five Batches by Validated Methods: Final Report. Project Number: D42226/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 79p.	•	Pass (14-Aug-2012)	
48896303	Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D42327/DCR. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6302/Color	Pass (t4-Aug-2012)	
48896303	Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D42327/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6303/Physical state	Pass (14-Aug-2012)	
48896303	Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Appearance (Color, Physical State and Odor)": Final Report. Project Number: D42327/OCR, Unpublished study prepared by Harlan Laboratories, Ltd. 24p.	830.6304/Odor	Pass (f4-Aug-2012)	
48895304	Schoop, T. (2012) 104.16: Determination of Oxidation/Reduction: Chemical Incompatibility: Final Report. Project Number: D42305/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 33p.	830.6314/Oxidizing or reducing action	Pass (14-Aug-2012)	
48896305	Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "Flash Point": Final Report. Project Number: D42316/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 29p.	830.6315/Flammability	Pass (14-Aug-2012)	
48896306	Kuhne, M. (2011) 104.16; "Determination of the Physico-Chemical Property "Viscosity". Project Number: D42272/OCR. Unpublished study prepared by Harlan Laboratories, Ltd. 33p.	830.7100/Viscosity	Pass (14-Aug-2012)	
48896307	Kuhne, M. (2011) 104.16: Determination of the Physico-Chemical Property "pH": Final Report. Project Number: D42294/OCR. Unpublished study prepared by Harlan Laboratories, L1d. 27p.		Pass (14-Aug-2012)	

Page 3

DP#: (407438)

* * * Product and Data Package Ingredients * * *

Decision#: (468313)

PC Code	CAS	Ingredient Name
129032	95737-68-1	Pyriproxyfen
129121	120068-37-3	Fipronil
109701	52645-53-1	Permethrin
109701	52645-53-1	Permethrin(44.8%)
129032	95737-68-1	Pyriproxyfen(1.8%)
129121	120068-37-3	Fipronil(6%)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

Date: February 18, 2013

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 407443 Decision no.: 468313 Submission no: 921393 Action code: R310

Product Name: Effitix TM Plus Topical Solution for Dogs

EPA Reg. No or File Symbol: 2382-ROE

Formulation Type: RTU spot-on

Ingredients statement from the label with PC codes included: 6.0% fipronil (pc code: 129121) 44.8% permethrin (pc code: 109701) and 1.8% pyriproxyfen (pc code: 129032) Application rate(s) of product: prescribed sized vials are applied. The number of vials

applied to an animal is dependent upon animal weight.

Use pattern: dog spot-on products OCSPP Guidelines: 810.3300

I. Action Requested: Review cited studies and new product label.

II. Background: Registrant cited data and submitted one MRID that summarizes the cited efficacy data. The label for this product is the same as for EPA Reg. No. 2382-187, Effitix Topical Solution for Dogs, which contains 6.0% fipronil and 44.8% permethrin - the same level of adulticides found in the pending product. The insect growth regulator (IGR) the pyriproxyfen at a concentration of 1.8% has been added to the pending product to effect flea development. The new directions and marketing claims are based on the activity of this IGR against fleas.

III. Study Reviews:

MRID 48896314 Summary of Efficaey Data for Effitix Plus Topical Solution for Dogs.

This volume summarizes the finding and data in the following studies:

Virbac data: 48510701, 48467122, 48467123, 48467124, 48467125, 48467126, 48446127, 48446128, 48467129

Fipronil efficacy data:

Merial: 43212114, 43212115, 43212116, 43212119, 43212120, 43212121, 43212122, 43444901, 435777701, 43577712, 43577713, 43951701, 44088901, 44942011, 44942106, 45618501, 45620502, 45620503, 45628104, 45628105, 45866901, 43577712, 43121114, 43121115, 43121117, 43121122, 43121118, 45620504, 45620505, 45620506, 43444901, 43577701, 43951701, 45612701, 45620503, 45866901, 45620501, 45628102, 45628103, 45628201, 45866902, 46019202, 46019201

Coopers' Animal Health: 41038802, 41038803

Hartz Mountain Corporation: 431372202, 431372203, 43111607

Ecto Development Corporation: 43396409, 43396410, 41683903, 43396409, 43396410

Wellmark: 46006002, Bayer: 46978901

Permethrin efficacy data:

Cooper's Animal Health: 42256901

Ecto Development Corporation: 43396409 and 43396410

Pyriproxyfen efficacy data:

Virbac AH, Inc.: 44900904 and 45020601

IV. ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

- 1. The label is acceptable provided the following marketing claims are removed:
 - "Prevents all immature flea stages in the dog's environment from developing."
 - "Sterilizes and kills adult fleas.".



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

January 11, 2013

MEMORANDUM: Acute Toxicity DERs for 2382-ROE

Subject:

Name of Pesticide Product:

EFFITIXTM PLUS TOPICAL SOLUTION FOR DOGS

Byran T. 13 och Jan 11-2013

EPA Reg. No. /File Symbol: 2382-ROE

DP Barcode:

DP 407435 468313

Decision No.: Action Code:

R310

PC Code:

109701 (Permethrin: 44.6%)

129121 (Fipronil: 6.0%)

129032 (Pyriproxyfen: 1.8%)

From:

Byron T. Backus, Ph.D., Toxicologist

Technical Review Branch

Registration Division (7505P)

To:

Driss Benmhend/Richard Gebken RM 10

Insecticide Branch

Registration Division (7505P)

Registrant:

VIRBAC AH, INC.

FORMULATION FROM LABEL:

Active Ingredient(s):		<u>by wt.</u>
129121 Fipronil		6.0%
109701 Permethrin		44.8%
129032 Pyriproxyfen		1.8%
Other Ingredients:		47.4%
	TOTAL	100.0%

ACTION REQUESTED: "Virbac has requested the registration of this fipronil/permethrin/nylar product... This is the acute toxicology package. All of the studies referenced are in Documentum, so there are no hard copies to send with this bean."

COMMENTS AND RECOMMENDATIONS:

- The five acute toxicity studies (MRIDs 48896309 through 48896313) have been classified as
 acceptable, and TRB concludes that a waiver of the inhalation study (with assignment to toxicity
 category IV by this exposure route) is appropriate. These five studies and the inhalation study
 waiver satisfy the acute toxicity data requirements for the registration of EPA File Symbol 2382ROE.
- 2. Based on the results of the five studies and inhalation study waiver, the following is the acute toxicity profile of EPA File Symbol 2382-ROE:

Acute oral toxicity	III	Acceptable	MRID 48896309
Acute dermal toxicity	I11	Acceptable	MRID 48896310
Acute inhalation toxicity	lV	Waived	n/a
Primary Eye irritation	IlI	Acceptable	MRID 48896311
Primary Dermal Irritation	IV	Acceptable	MRID 48896312
Dermal Sensitization	Negative	Acceptable	MRID 48896313

3. Based on the acute toxicity profile as well as information from the Confidential Statement of Formula and the uses indicated on the proposed label, the following is the precautionary and first aid labeling for 2382-ROE as obtained from the TRB Label Review System:

PRODUCT ID #: 002382-00192

PRODUCT NAME: EFFITEX® PLUS TOPICAL SOLUTION FOR DOGS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

First Aid:

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

^{*[}Protective eyewear may be specified, if appropriate].

If in eyes:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

- 4. This memorandum addresses only the acute toxicity data requirements for 2382-ROE; the companion animal safety data requirements for this product will be addressed in a separate action.
- 5. The TRB Chemistry Team should review and accept the CSF dated July 12, 2012.

Reviewer: Byron T. Backus, Ph.D. Date: January 11, 2013

Risk Manager (EPA): 10

The following table is the Acute Toxicity Data Evaluation Record (DER) for the five studies and inhalation toxicity waiver request supporting the proposed product, File Symbol 2382-ROE:

1. DP BARCODE: 407435							
2. PC CODES: 109701 (Permethrin: 44.6%), 129121 (Fipronil: 6.0%), 129032 (Pyriproxyfen:							
1.8%)							
3. CURRENT DATE: January 11, 2013							
Test material: test item 104.16, batch no. NDE 11257-2, a clear yellowish solution containing 6.6%							
		6 w/v permethrin. Density: 1.114 g/cr					
Study/Species/Lab	MRID	Results	Tox	Core			
Study #/Date	1000/000	T 75 (7) 0000 (1 5) (0 1 1	Cat	Grade			
Acute oral toxicity / rat	48896309	$LD_{50}(F) = 2000 \text{ mg/kg} [1/3 \text{ dosed}]$	III	A			
Harlan Laboratories, 4452		at 2000 mg/kg died]; Mortality:					
Itingen, Switzerland / Harlan		550 mg/kg: 0/1; 2000 mg/kg: 1/3					
Laboratories Study D42171 /		(total of 4 animals dosed). Signs of					
Jan. 13, 2012 / OCSPP		toxicity: 550 mg/kg: dragging of					
870.1100; OECD 425		limbs, straub phenomenon (tail					
Address of the Control of the Contro		rigid; erected across back in an S-					
WHITTHE		shaped curve), hunched posture on days 1-3, tachypnea on day 1,					
		muscle twitching, decreased					
		activity and/or ruffled fur on days					
PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE PR		2-3; similar effects were observed					
		in the 2000 mg/kg animals. Rat					
		that died did so on day 7. Gross					
		necropsy: decedent had					
		discoloured and dark red lungs;					
	444	survivors were normal.					
Acute dermal toxicity / rat	48896310	$LD_{50} > 2000$ mg/kg (both sexes).	III	A			
Harlan Laboratories, 4452		No deaths. IM & IF vocalized					
ltingen, Switzerland / Harlan		after being touched on day 1;					
Laboratories Study D42182 /		otherwise no abnormal systemic					
Jan. 13, 2012 / OCSPP		effects. 1M & 1F showed slight					
870.1200; OECD 402		erythema on day 2. No abnormal					
- -		findings at necropsy. 1M & 2F had					
		slight weight losses day 1-8; all					
		had wt gains day 1-15.					
Acute inhalation toxicity / rat	n/a	Vapor pressures of all 3 actives	ΙV	W			
Waiver Request / OCSPP		very low; maximum volume that					
870.1300; OECD 403		could be administered to a dog at					
		one time would be 6 mL.					

Primary eye irritation / rabbit Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42193 / Jan. 16, 2012 / OCSPP 870.2400; OECD 405	48896311	At 1 & 24 hrs 1/3 eyes was positive for conjunctival redness (score of 2). None of the eyes was positive at 48 hrs or subsequently. MMTS = 6.67 at 1 hr.	III	A
Primary dermal irritation / rabbit / Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42204 / Jan. 13, 2012/ OCSPP 870.2500; OECD 404	48896312	All sites scored 2 for erythema at 1 hr., and one site also scored 1 for edema. At 24 hrs all sites scored 1 for erythema and one site also scored 1 for edema. At 48 hrs one site scored 1 for erythema; at 72 hrs all scores were zero. PII = 1.00; mean irritation score at 72 hrs = 0.00.	IV	A
Dermal sensitization (Buehler)/ guinea pig / Harlan Laboratories, 4452 Itingen, Switzerland / Harlan Laboratories Study D42215 / March 21, 2012 / OCSPP 870.2600; OECD 429	48896313	A concentration of I00% was used for induction and 15% in diethylene glycol monomethyl ether was used for challenge.	Non sen- si- tizer	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap n/a = "not applicable"



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

January 15, 2013

MEMORANDUM: Companion Animal Study Citations for 2382-ROE

Subject:

Name of Pesticide Product: EFFITIXTM PLUS TOPICAL SOLUTION FOR DOGS

EPA Reg. No. /File Symbol: 2382-ROE

DP Barcode:

DP 407441

Decision No.:

468313

Action Code:

R310

PC Code:

109701 (Permethrin: 44.6%)

129121 (Fipronil: 6.0%)

129032 (Pyriproxyfen: 1.8%) Byron T. Bookers
Jan -15-2013 Melaslin
T. L. TOXICOLOGY

From:

Byron T. Backus, Ph.D., Toxicologist

Technical Review Branch

Registration Division (7505P)

To:

Driss Benmhend/Richard Gebken RM 10

Insecticide Branch

Registration Division (7505P)

Registrant:

VIRBAC AH, INC.

FORMULATION FROM LABEL:

Active Ingredient(s):		by wt.
129121 Fipronil		6.0%
109701 Permethrin		44.8%
129032 Pyriproxyfen		1.8%
Other Ingredients:		47.4%
	TOTAL	100.0%

ACTION REQUESTED: "Virbac has requested the registration of this fipronil/permethrin/nylar product. I'm requesting an expedited review... This is the Companion Animal Safety study. The minimum size for the dog was not provided on the label..."

COMMENTS AND RECOMMENDATIONS:

- 1. This package includes a listing of 29 previously submitted companion animal safety studies.

 Copies of the data matrix, proposed label and other documents are available from Documentum.
- 2. Virbac has previously registered (EPA Reg. No. 2382-187) a dog spot-on product with a label declaration of 6.01% Fipronil and 44.88% Permethrin as active ingredients. The additional active in 2382-ROE, Pyriproxyfen (or Nylar), has been demonstrated to have a very low toxicity to dogs, as shown in a 52-week capsule feeding study (MRID 42178309, included in the data matrix citations for 2382-ROE). The companion animal safety studies that were conducted on and/or used to support 2382-187 can also be used to support 2382-ROE, and can also be used by the Agency to set dosage levels. The proposed dosage rates for 2382-ROE are the same as those given on the last accepted (August 28, 2012) label for 2382-187.
- 3. In a TRB review dated October 13, 2011 it was concluded that in a study in adult beagles (MRID 48467117) the margin of safety in 10- to 20-kg adult beagle dogs administered 104.05 [End-use Product: EffitixTM Topical Solution for Dogs] is at least 5x the recommended dose (2.0 mL/dog). This companion animal safety study in dogs was classified as **Acceptable/Guideline**.
 - However, there were two companion animal safety studies (MRIDs 48467118 and 48487302) with 8 week old beagle puppies in which severe adverse effects were seen at the 5X level (5.0 mL/puppy). Both of these studies were classified as Unacceptable/Guideline because an adequate margin of safety was not demonstrated. However, no adverse effects were observed at the 3X level (3.0 mL/puppy).
- 4. EPA Reg. 2382-187 was registered for use on dogs 12 weeks of age and older with a minimum dosage rate of 1.0 mL for dogs weighing less than 22.9 lbs. The registrant then proposed a new dosage rate of 0.5 mL for application to puppies to puppies 8 weeks of age or older and small dogs weighing between 4 and 10.9 lbs. This was accepted (because no adverse effects had been observed at the 3.0 mL/puppy dose in MRID 48467118) in a TRB memorandum dated August 13, 2012. The maximum dosage rate of 0.5 mL to a 4-lb dog is equivalent to 0.28 mL/kg.
- 5. Virbac subsequently submitted a study (MRID 48951001, not included in the list of studies cited by the registrant for 2382-ROE) on 10-week old beagle puppies as 6(a)(2) data. The adverse effects (including uncontrollable seizures which resulted in the euthanasia of one puppy) that occurred demonstrated that a dosage rate of 1.0 mL/puppy has a less than adequate (5X) margin of safety. The puppy that was euthanized was a male weighing 4.08 kg that received 5.0 mL, equivalent to 1.23 mL/kg; which when divided by 5 gives 0.245 mL/kg. In a review dated December 17, 2012 TRB recommended resetting the minimum weight to 5 lbs (=2.27 kg) which would result in a maximum 1X dosage rate of 0.22 mL/kg.
- 6. The cited companion animal safety studies adequately support the proposed uses for 2382-ROE, except the label dosage rates should be revised to specify 5 lbs as the minimum weight rather than 4 lbs.

Please read instructions on reverse	before completing form		Form Approved, OMB N	lo. 2070-0060, Approval expires 5-31-98
	Unite	ed States	X Registration	
♦EPA	Environmental	Protection Agency	Amendme	nt
	Washing	on, DC 20460	Other	
		lication for Pesticide - Se	ction	
t. Company/Product Number		2. EPA Produ	ct Manager	3. Proposed Classification
Virbac AH, Inc./ 2382-xxx 4. Company/Product [Name)		Richard Gebke	<u>Pn</u>	₩ None
EFFIT!X™PLUS Topica! Soluti	ion for Dogs	l to		X None Restricted
5. Name and Address of Appli	cant (Include ZIP Code)			e with FIFRA Section 3(c)(3)
Virbac AH, Inc P.O. Box 162059		(b)(i), my prod to:	uct is similar or lidentica	at in composition and labeling
Fort Worth, TX 76161	•	EPA Reg No.		
Charle of this is a second	Jun	Bradush Nama		
Check if this is a new add	ness	Product Name		
		Section - II		
Amendment – Explain be	low		rinted labels in respons	e to
<u> </u>		Agency	letter dated	
Resubmission in respons	e to Agency letter dated	*Me To	o" Application	
L		استسبا		
Notification – Explain belo	wo	X Olher-	- Explain below	
[L]				
Explanation: Use additional p	age(s) if necessary. (For	Section I and Section !!.)		
Application for EFEITIX F	PLUS new product re	egistration. PRIA Category i	R310 Please refer	to attached letter
Application to El TIX	LOO HEW PRODUCE	egiatration. Trita Category i	NO SO. 1 REAGE TOPE	to attached tetter.
		Section III		
1. Material This Product Will b				La =
Child-Resistant Packaging X Yes	Unit Packaging X Yes	Water Soluble Pack	kaging	Type of Container Metal
	<u> </u>	X No		X Plastic, PETE
No	No No			Glass
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per It "Yes" container Package wgt	No. per container	Paper Other (Specify)
de Submitted	0.5	1,3,6,36	Containor	L Bittlet (Opecity)
3. Location of Net Contents In	<u>formation</u>	4. Size(s) Retail Container		ation of label directions
Label	c Container	1, 3, 6 ml tubes		on Label
6. Manner in Which Label is A	ffixed to Product	Lithograph	Other	In Label accompanying product
vitalities of a suited wheel in a		X Paper glued		
		Stenciled		
		Section IV		
1. Contact Person (Completa i Name	iems directly below for id	entification of individual to be confi Title		process this application.) one No. (Include Area Code)
Craig Parks, MS, DVM		Vice President of Research		7-3576
		Oevelopment,		
	Car	Virbac AH, Inc.		6. Date Application
I cerrify that the statements I ha		all attachments thereto are true, ac	curate and complete,	Received
	gty fatse or misleading stat	ement may be punishable by fine or	imprisonment or	
botb under applicable law 2. Signature	<u>, ,</u>	3. Title		(Stamped)
1 1		Vice President of Research	and Development,	
Cinin tanh		Virbac AH, Inc.		
1				1
4 Typed Name		5 Date		 [
4. Typed Name Craig Parks, MS, DVM		5. Date August 3, 2012	White - EPA File Copy	(Original) Yellow – Applicant Copy



July 24, 2012

U.S. Bank Government Lockbox 979074 1005 Convention Plaza SL-MO-C2-GL St. Louis, MO 63197

RE: Check for 2012 PRIA Fees; Virbac AH, Inc. (EPA Co. Number 2382)

Dear Sir or Madam:

Please find enclosed a check numbered 1016276 made out to the Environmental Protection Agency (EPA) in the amount of \$4,807.00. This check fulfills the financial obligations in support of an animal health pesticide, to be registered under the company Virbac AH, Inc. (EPA Company Number 2382). Also attached for reference are copies of the EPA Form 8570-1 with information on the registration of the with EPA.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Vice President, Research & Development

Virbac Animal Health, Inc.

Product ingredient source information may be entitled to confidential treatment

		Form Approved, OMB No. 2070-0060. Approval expires 5-31-98		
United States				
	Environmental Protection Age	ncy		
⊕EPA	Washington, DC 20460			
For	mulator's Exemption Sta	tement		
	(40 CFR 152.85)			
Applicant's Name and Address		le Symbol/Registration Number		
Virbae Animal Health	2382-N			
P. O. Box 162059	Produc			
Ft. Worth, TX 76137		XTM PLUS Topical Solution for Dogs		
	Date of July 12,	Confidential Statement of Formula (EPA Form 8570-4)		
As an authorized representative of the applicant				
11	1	, , , , , , , , , , , , , , , , , , ,		
(1) This product contains the following active in	gredient(s):permethrin			
(2) Of these, each active ingredient listed in par				
		active ingredient which is registered under FIFRA		
, , , , , , , , , , , , , , , , , , , ,	producer, and is labeled for at least e	ach use for which my product is proposed to be		
labeled.		•		
(3) Indicate by checking (A) or (B) below whic	h paragraph applies:			
		the above identified product is attached to this		
statement. That formula statement indicates, by company name, registration number, and product name, the source of the				
active ingredient(s) listed in paragra	iph (I)			
OR				
(B) The Confidential Statement of Form	ula (CSF) (FPA Form 8750-4) refer	enced above and on file with the EPA is complete,		
	he information required on the curren			
	•			
(4) The following active ingredients in this production	luct qualify for the formulator's exer	nption		
	Source			
	B 3 4 3	B 14 (2 N)		
Active Ingredient	Product Name	Registration Number		
Permethrin				
2 ormania in				
Pyriproxyfen				

Name and Title Vice President, Research & Development

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy Yellow - Applicant copy

Date

August 3, 2012

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named EFFITIXTM Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
TRANSMIT	TTAL DOCUMENT	48896300
, 1	Product Specific Chemistry For Effitix TM Plus Topical Solution for Dogs	48896301
2	Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxifen in Five Batches by Validated Methods	48896302
3	Determination of the physic-Chemical Property Appearance (Color, Physical State, and Odor) (D42327)	48896303
4	Determination of Oxidation/reduction: Chemnical Incompatability (D42305)	48896304
5 7	Determination of the Physico-Chemical Property "Flash Point" (D42316)	48896305
⁶	Determination of the Physico-Chemical Property Viscosity (D42272)	48896306
7	Determination of the Physico-Chemical Property pH (D42294)	48896307
, 8	Determination of the Physico-Chemical Property Relative Density (D42283)	48896308
4 9	Acute oral toxicity (D42171)	48896309
` 10	Acute dermal toxicity (D42182)	48896310
11	Primary eye irritation (D42193)	48896311
12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix TM Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix TM Plus Topical Solution for Dogs	48896315



August 2, 2012

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject:

EFFITIX™ PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);

New Product Application.

Dear Mr. Gebken.

Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382) is hereby submitting an application to register the spot-on pesticide product EFFITIX™ PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil at 6.0% w/w, permethrin at 44.8%, and pyriproxyfen at 1.8 % w/w and is intended to control fleas, ticks, mosquitoes, and other pests in dogs only.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Virbac is issuing Offer to Pay letters to the submitters of data not owned by Virbac and cited in this application that were originally submitted to EPA within the past 15 years.

Below is a list of the components included with this application:

1.	Cover Letter;	
2.	Transmittal Document;	
3.	Application for Pesticide Form 8570-1 for EFFITIX™ PLUS Topical Solution I	or Dogs;
4.	Confidential Statement of Formula for EFFITIX™ PLUS Topical Solution for I)ogg;•• • • • •
5.	Data Matrix Form 8570-4 for EFFITIX™ PLUS Topical Solution for Dogs;	
6.	Certification of Data Citation Form 8570-34 For EFFITIX™ PLUS Topical Sol	ution For
	Dogs;	****
7.	Proposed Use Directions for EFFITIX TM Topical Solution for Dogs - 5 copies;	*****
8.	3 copies of bound PR 86-5 compliant study reports supporting registration;	** · * a
9.	Waiver Request for Acute Inhalation Study (attached to Cover Letter);	• ••
10.	Letter of Self-certification of Child-Resistant Packaging;	: : .
11.	Copy of PRIA Check for category R-310 (\$4807).	•
		: • • •

Child-Resistant Packaging Testing & Data

EFFITIXTM PLUS Topical Solution for Dogs and will be marketed in single dose unit applicators that have been previously reviewed and approved by EPA as Child Resistant under the registration of EFFITIXTM Topical Solution for Dogs, (EPA Reg. No. 2382-187) and EFFIPRO Topical Solution For Cats (2382-186). Included with this submission is an updated Data Matrix citing all previously submitted data supporting CRP certification of the proposed presentations of EFFITIX PLUS. In addition, an updated CRP certification letter has been provided.

PRIA Considerations

After reviewing the Agency's PRIA category interpretations, we believe that the R-310 PRIA category and a 6 month review period is appropriate for this new product application. Consequently, please find a copy of one previously submitted check in the amount of \$4807 to cover the PRIA fee.

Should you have any questions about this application package, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Craig take

Vice President, Research & Development

Virbac Animal Health, Inc.

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named $EFFITIX^{TM}$ Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
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12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix TM Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix TM Plus Topical Solution for Dogs	48896315

Waiver Request

Registrant: Virbac Animal Health, Inc. Acute Inhalation Study (OPPTS 830.1300). Brandname: Effitix[™] PLUS Topical Solution for Dogs.

The Effitix PLUS Topical Solution for Dogs product is composed of 6.0% w/w of the active ingredient fipronil, 44.8% w/w of the active ingredient permethrin and 1.8% w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be neglible. Only very small amounts of product are applied per application, depending the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effitix PLUS Topical Solution that can be administered at one time to a pet using the largest available applicator size is approximately 6.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of all three active ingredients fipronil permethrin, and pyriproxifen are extremely low (2.8 x 10⁻⁹ mm Hg @ 25°C, 2.18 x 10⁻⁸ mm Hg @ 25°C, and 1.0 x 10⁻⁷ mm Hg @ 20⁰ C, respectively) indicating that all three active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.

Form Approved OMB No. 20 0-0050

2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

Paper work Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

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PO Box 162059 Fort Worth TX 76161 tagredient: Fipronil, Permethrin, Pyriproxifen Guideline Reference Number Guideline Study Name MRID Number Submitter Status Product Chemistry 830 Series Group A Test Guidelines 830.1550 Product Identity and Composition New Submission Virbac AH, Inc. OWN 830.1600 Description of Materials Used New Submission Virbac AH, Inc. OWN 830.1620 Description of Production Process New Submission Virbac AH, Inc. OWN 830.1650 Description of Fornulation Process New Submission Virbac AH, Inc. OWN 830.1670 Description of Fornulation Process New Submission Virbac AH, Inc. OWN 830.1750 Certified Limits New Submission Virbac AH, Inc. OWN 830.1750 Certified Limits New Submission Virbac AH, Inc. OWN 830.1700, 830.1800 Analytical Method New Submission Virbac AH, Inc. OWN 830.6302 Color New Submission Virbac AH, Inc. OWN 830.6303 Physical State New Submission Virbac AH, Inc. OWN 830.6304 Odor New Submission Virbac AH, Inc. OWN 830.6315 Flammability New Submission Virbac AH, Inc. OWN 830.6316 Explodability New Submission Virbac AH, Inc. OWN 830.6317 Storage stability To Be Conducted Virbac AH, Inc. OWN 830.6317 Name and Title		Arhitress				<u> </u>
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Metal Stability Virbac AH, Inc. NR	830.6303	Physical State	New Submission	Virbac AH, Inc.	OWN	1
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830.6316 Explodability Virbae AH, Inc NR 830.6317 Storage stability To Be Conducted Virbae AH, Inc. OWN Signature Name and Title	830.6314	Oxidation/reduction	New Submission	Virbac AH, Inc	OWN	<u> </u>
830.6317 Storage stability To Be Conducted Virbac AH, Inc. OWN Signature Name and Title	830.6315	Flammability	New Submission	Virbae AH, Inc.	OWN	
Signature Name and Title	830.6316	Explodability		Virbue AH, Inc	NR	
larn (Storage stability	To Be Conducted		OWN	
Cray take	_			Craig Parks		Date July 31, 2012
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	DA	ATA MATRIX			
Date: July 31, 2012			EPA Rcg. No./File Symbol 2382- TBA		Page 2 of 1
Applicant's/Registrant's Name & A	ddress		Product:		
Virbac AH, Inc					
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTION I	OR DOGS	
Fort Worth TX 76161	-iir				<u> </u>
Ing/edient: Fipronil, Permethrin.Py Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Stahis	Note
		14Kii2 Kuilloei	3.ibinitici	Stanis	14010
Product Chemistry 830 Series					
830.7100	Viscosity	New Submission	Virbac Al·I, Inc.	OWN	
830.6319	Miscibility		Virbac AH, Inc	NR	
830.6320	Corrosion characteristics	To Be Conducted	Virbne AH, Inc.	OWN	
830.6321	Dielectric breakdown voltage		Virbac AH, Inc	NR	
830,7000	pH	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc	OWN	
830.7320	Particle Size distribution		Virbac AH, Inc.	NR	
40 CFR 158,340 Toxicology Da	ala Requirements	•			
870.1100	Acute oral loxicity	New Submission	Virbac AH, Inc.	OWN	
870,1200	Acute dermal loxicity	New Submission	Virbac AH, Inc	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbae AH, Inc.	OWN	waiver
870.2400	Primary eye initation	New Submission	Virbac AH, Inc	OWN	
870.2500	Primary dermal irritation	New Submission	Virbae AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc	OWN	
Signature			Name and Title		Date
			Craig Parks		July 31,
Craig Rah			Vice President, Research & Development		2012
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Date: July 31, 2012 Applicant's/Registrant's Name & Addres Virbae AH, Inc 1'O Box 162059 Fort Worth 'TX 76161 Ingredient: Fipromil, Permethria. Pyriptox Gnideline Reference Number		AMBIE	EPA Reg. No./File Symbol 2382- TBA Product: EFFITIX TM TOPICAL SOLUTION FOR DO		Page 3 of 11
Virbae AH, Inc 10 Box 162059 Fort Worth TX 76161 Ingredient: Fipromil, Permethria Pyriptox Guideline Reference Number	xifen				
Fort Worth 't'X 76161 Ingredient: Fipromil, Permethria Pyriptox Gnideline Reference Number			DEDUTIN THE COLUMN POR DO		
Ingredient: Fipromi, Permethria Pyriprox Guideline Reference Number			EPPTIA "" TOPICAL SOLUTION FOR DO	GS	
Guideline Reference Number					<u> </u>
	Guidenne Study Rame	MRID Number	Submitter	Status	Note
Efficacy and Safety Data					
870.7200	Companion Animal safety 14 d pup study-I	48487302	Virtue AH, Inc	OWN	
870.7200	Companion Animal safety-Beagle Dog	48467117	Virbac AH, Inc.	OWN	
870.7200	Companion Animal safety-14 d pup study-2	48467118	Virbac AH, Inc.	OWN	<u> </u>
870.7200	Companion Animal safety Summary	48467119	Virbae AH, Inc	OWN	T
870.7200	Companion Animal safety - Melhod Valid,	48467120	Virbae AH, Inc	OWN	
810.3300	Product Performance -Flea onset of Action	48510701	Virbae AH, Inc	OWN	
810.3300	Product Performance - Rhimiciphalus action	48467122	Viroac AH, Inc.	OWN	
810.3300	Product Performance -D. variablis action	48467123	Virbae AH, Inc	OWN	
810,3300	Product Performance - Shannoo study	48467124	Virbac AH, Inc	OWN	
810.3300	Product Performance - Amblyonia efficacy	48467125	Virbae AH, Inc	OWN	
810,3300	Product Performance - Ixodes efficacy	48467126	Virbae Al-I, Inc.	ÖWN	
810.3300	Product Performance - Mosquito efficacy	48467127	Virbae AH, Inc	OWN	
810.3300	Product Performance - Tick repellency	48467128	Virbae AH, Inc	OWN	
810,3300	Product Performance - Efficacy Summary	48467129	Virbac AH, Inc.	OWN	
Efficacy and Safety Data-				1	
Figronil		}		1	}
870.7200	Companion Animal safety	43444905	Merial	OLD	
870,7200	Continuion Aminal safety	43577711	Merial	OLD	
870.7200	Companion Animal safety	43863802	Merial	OLD	
870.7200	Companion Animal safety	43121110	Merial	OLD	
870.7200	Companion Animal safety	43121111	Merial	OLD	
870.7200	Companion Animal safety	45612702	Merial	PAY	
Signature		 	Name and Title		Date
Craig Kahn		-	Craig Parks Vice President, Research & Development		ภาโy 31, 2012

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Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA	EPA Reg. No./File Symbol 2382-TBA		
Applicant's/Registrant's Name & A	ddress		t ^a roduet;		
Virbae AH, Inc					
PO Box 162059			EFFITIX TAPLUS TOPICAL SOLUTION	FOR DOGS	
Fort Worth TX 76161					
Ingredient: Fipronil, Permethrin, Pyr Guideline Reference Number		MRID Number	Submitter	Status	Note
	Guideline Study Name	MICID Number	Shormiter	Stitus	Note
Efficacy and safely data					1
-Fipronil	1 1 1 1 C PC 7	(2121114	Montol 1	 0115	
810.3300	Product Performance - Efficacy-flea	43121114	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121115	Merial	OLD	
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810.3300	Product Performance - Efficacy-flea	43121122	Merial	OLD]
810.3300	Product Performance - Efficacy-flea	43444901	Merial	OLD	Ĩ
810.3300	Product Performance - Efficacy-flea	43577701	Merial	OLD	T
810.3300	Product Performance - Efficacy-flea	43577712	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43577713	Merial	OLD	1
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810.3300	Product Performance - Efficacy-flea	44088901	Merial	OLD	1
810.3300	Product Performance - Efficacy-flea	44942011	Merial	PAY	
Signature	· · ·	•	Name and Title		Date
Crany lake			Craig Parks		July 31,
Leavy tacher			Vice President, Research & Development		2012

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Date July 31, 2012		EPA Reg, No./File Symbol 2382-TBA		Page 5 of 11	
Applicant's/Registrant's Name & A	alriress		Product:		
Virbac AH, Inc					
PO Box 162059			EFFITIX THE PLUS TOPICAL SOLUTION	FOR DOGS	
Fort Worth TX 76161	1 to				.l
Ingredient Fipronil, Permethria Pyri		1 3 (0) 0 32			1 31 .
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and safety data	1	· ·		-	
-Fiproail					<u> </u>
810,3300	Product Performance - Efficacy-flea	44942106	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45618501	Merial	PAY]
810,3300	Product Performance - Efficacy-flea	45620502	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45620503	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45628104	Menal .	PAY	
810.3300	Product Performance - Efficacy-flea	45628105	Merial	PAY	
810.3300	Product Performance - Efficacy-flea	45866901	Merial	PAY	7
810.3300	Product Performance - Efficacy-tick	43577712	Merial	OLD	
810,3300	Product Performance - Efficacy-tick	43121114	Merial	OLD	
810.3300	Product Performance - Efficacy-tick	43121115	Merial	OLD	
810.3300	Product Performance - Efficacy-tick	43121117	Merial	OLD	
810.3300	Product Performance - Efficacy-tick	43121122	Merial	OLD	
810.3300	Product Performance- Efficacy Bathing	43121118	Morial	OLD	
Signature			Name and Title		Date
			Craig Parks		July 31,
Caning Keelen			Vice President, Research & Development		20 t2

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Applicant's/Registrant's Name & A	ıldress		Product:		
Virbae AH, Inc	•				1
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTION	FOR DOGS	
Fort Worth TX 76161					1
Ingredient: Pipronil, Permethrin.Pyr Guidgline Reference Number		MRID Number	I distriction		
	Guideline Study Name	MKID Number	Submitter	Status	Note
Efficacy and safely data					
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810.3300	Product Performance - Efficacy-Mange	45620504	Merial	PAY	-
810.3300	Product Performance - Efficacy-Mange	45620505	Merial	PAY	
810.3300	Product Performance - Efficacy-Mange	45620506	Merial	PAY	<u> </u>
810.3300	Product Performance - Efficacy-Mites	43444901	Merial	OLD	
810.3300	Product Performance - Efficacy-Mites	43577701	Merial	OLD	
810.3300	Product Performance - Efficacy-Mites	43951701	Merial	OLD	1.
810.3300	Product Performance - Efficacy-Miles	45612701	Meriul	ľAY	1
810.3300	Product Performance - Efficacy-Miles	45620503	Merial	PAY	
810.3300	Product Performance - Efficacy-Miles	45866901	Merial	PAY	
810,3300	Product Performance - Efficacy-Lice	45620501	Merial	PΛY	
810.3300	Product Performance - Efficacy-Lice	45628101	Merial	PAY	
810,3300	Product Performance - Efficacy-Lice	45628102	Merial	PAY	
810.3300	Product Performance - Efficacy-Lice	45628103	Merial	PAY	
810,3300	Product Performance - Efficacy-Lice	45628201	Merial	PAY	
810.3300	Product Performance - Efficacy-Mosquito	45866902	Merial	PAY	
810.3300	Product Performance - Efficacy-Mosquito	46019202	Merial	ŀΛΥ	
810.3300	Product Performance - Efficacy-Mosquito	46019201	Merial	PAY	
Signature			Name and Title	•	Date
Cong take			Craig l'arks		July 31,
Long tank			Vice President, Research & Development		2012

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Date July 31, 2012			EPA Reg. No./File Symbol 2382-TBA		Page 7 of 1
Applicant's/Registrant's Name & A	ddress		Product:		
Virbae AH, the					
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTION	FOR DOGS	
Fort Worth TX 76161 Ingredient: Pipronil, Permethrin.Pyr	i				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data-	Guideline Study (Name	MKID Rullog	Submitter	510123	11010
Permethrin					
870.7200	Companion Animal safety	41056906	Coopers Animal Health, Inc	OLD	
870.7200	Companion Animal safety	41953201	Coopers Animal Health, Inc.	OLD	
870.7200	Companion Animal safety	43137201	Hartz Mountain Corporation	QLD	
870.7200	Companion Animal safety	43447101	· Hartz Mountain Corporation	OLD	
870.7200	Companion Animal safety	43396408	ECTO Development Corporation	OLD	
870.7200	Companion Animal safety	43612601	ECTO Development Corporation	OLD	<u></u>
810.3300	Product Performance - Efficacy	41038802	Cooper's Animal Health	OLD	
810.3300	Product Performance - Efficacy	41038803	Cooper's Animal Health	OLD	
810,3300	Product Performance - Efficacy	43137202	Harlz Mountoin Corporation	OLD	
810.3300	Product Performance - Efficacy	43137203	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Perfozmance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	46006002	Wellmark	PUB	
810.3300	Product Performance - Efficacy	41683903	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43111607	Hartz Mountain Corporation	OLD	ł
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy-Biting Fly	46978901	Bayer Healthcare LLC	PAY	11-13-06
Signature			Name and fitte Craig Parks		Date July 31,
Cray lake			Vice President, Research & Development		2012
	Various April Ma. Submit puls Danet varion		Segues Intern		<u> </u>

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		DATA MATRIX			
Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TBA		Page 8 of 11
Applicant's/Registrant's Name & Ac	ldress		1'roduct;	······································	1
Virbae All, Inc					[
PO Box 162059			EFFITIX ™ TOPICAL SOLUTION FOR D	OGS	
Fort Worth TX 76161					
Ingredient; Finronil, Permethrin Pyri		Lauren St. Marie	La Live	······································	Y
Guideline Iteference Number	Gnideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data-					ļ
Permethrin					
810.3300	Product Performance - Efficacy	42256901	Cooper's Animal Health, Inc.	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
Efficacy and Safety Data-					
Pyriproxifcu					
870.7200	Companion Animal safety	43396408	Ecto Development Corporation	OLD	
870,7200	Companion Animal Safety	43612601	Ecto Development Corporation	OLD	
870.7200	Companion Animal Safety	44900902	Virbae AH, Inc.	OWN	<u> </u>
870.7200	Companion Animal Safety	44900903	Virbae AH, Inc.	OWN	1
870.7200	Companion Animal Safety	42178309	Sumitomo Chemical Company, Ltd.	OLD	1
&10.3300	Product Performance - Efficacy	44900904	Virbae Al-I, Inc.	OWN	
810.3300	I'rodnet Performance - Efficacy	45020601	Vírbac AH, Inc.	OWN	j
Signoture			Name and Title		Date
Craig hah			Craig Parks		July 31,
Cracy take			Vice President, Research & Development		2012
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	DAT	TA MATRIX			
Date: July 31, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 9 of 11	
	rant's Name & Arhlress		Product:		
Virbac All, Inc					
PO Box 162059			EFFITIX IM PLUS TOPICAL SOLUTIO	N FOR DOGS	
Fort Worth TX 76					<u> </u>
Guideline Referen	il, Permethrin Pyriproxifen ce Number Guideline Study Name	MRID Number	Submitter	Status	Note
Child Resistant		.,,			
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 1 applicator tube test as a Poison Frevention Package for Virbae SA	48467130	Virbae AH, Inc.	OWN	
40 CFR 157	Evaluation of the Irul Applicator Tube with 1.0 ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467131	Virbae Al-I, Inc	OWN	
40 CFR 157	Evoluation of the 1ml Applicator Tube with 1.0 ml water, 6 applicator tubes test as n Poison Prevention Package for Virbae SA	48467132	Virbae AH, Inc.	OWN	
0 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbae	48467133	Virbae AH, Inc	OWN	
10 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbae SA	18467134	Virbae AH, Inc.	OWN	
10 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbae SA	48467135	Virbae AH, Inc	OWN	
10 CFR 157	Evaluation of the 3rd Applicator Tube with 2.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbac SA	48467136	Virbae AH, Inc.	OWN	
Signature Leavy &			Name and Title Craig Parks Vice President, Research & Development	-	Date July 31, 2012

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	DAT	A MATRIX	·		
Date: July 12, 2012		EPA Reg. No./File Symbol 2382-TBA		Page 10 of 1 t	
	nt's Name & Address		Product:		
Virbac AH, Inc			P17779137 YU 10 116 450450 4 1 50 1 100 100	COD DOGG	
I'O Box 162059 Fort Worth TX 7616	.1		EFFITIX TAI PLUS TOPICAL SOLUTION	FOR DOGS	
	Permethrin.Pyriproxifen		I		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbac SA	48467137	Virhac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 1 applicator tube test as a Poison Prevention Package for Virtue SA	48467138	Virbae AII, Inc	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 3 applicator tubes test as a Poison Prevention Package for Vibae SA	48467139	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 6 applicator tubes test as a Poison trevention Package for Vinhae SA	48467140	Virbae All, Inc	OWN	
40 CFR 157	Evaluation of the 6ml Applicator fube with 4.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbae SA	48467141	Virbae All, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbae SA	48467142	Virbae AH, Inc	OWN	Vol 43
Signature			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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	DATA	MATRIX			
Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TBA		Page 11 of 1
Applicant's/Registrant	's Name & Address		Product:		
Virbae Alf, Inc			DUDING THE BUILDING A COLUMN		ĺ
PO Box 162059 Fort Worth TX 76161			EFFITIX ™ PŁUS TOPICAL SOLI	JITON FOR DOGS	
· · · · · · · · · · · · · · · · · · ·	ermethrin Pyriproxifen				<u></u>
Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
Number		THE PERSON NAMED OF	Scommer	Statilia	I TOIL
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbae SA	48467143	Virbae AH, Inc.	OWN	·
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water,6 applicator tubes test as a Poison Prevention Package Virbae SA	48467144	Virbae AH, Inc	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water,36 applicator tubes test as n Poison Prevention Package for Virbae SA	48467145	Virbae All, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095215	Virbae AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095216	Virbac AH, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095217	Virbae All, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube lest for Senior-Use Effectiveness	48095218	Virbae AH, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095219	Virbae AH, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095220	Virbae AH, Inc	OWN	
40 CFR 157	Evaluation of the tml applicator tube with 0.50 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410018	Virbae AH, Inc	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Senior-Use Effectiveness	48410019	Virbae AH, Inc	OWN	
Signature			Name and Title		Date
Craig Kahn			Craig Parks Vice President, Research & Develop	ment	July 31, 2012
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Product ingredient source information may be entitled to confidential treatment

		ed. OMB No. 2070-0060. Approval expires 5-31-98					
	United States						
	Environmental Protection Agency Washington, DC 20460						
To me	-						
ron	mulator's Exemption Statement						
Applicant's Name and Address	(40 CFR 152.85)	Ondistantia Number					
Virbac Animal Health	2382-NEW	Registration Number					
P. O. Box 162059	Product Name						
Ft. Worth, TX 76137		Topical Solution for Dogs					
	Date of Confidenti July 12, 2012	al Statement of Formula (EPA Form 8570-4)					
As an authorized representative of the applicant		I certify that:					
	••••••••••••••••••••••••••••••••••••••						
(1) This product contains the following active in	gredient(s):permethrin						
(0) 004							
(2) Of these, each active ingredient listed in particular formulation or reprehensing	agraph (4) is present solely as the result of the t another product which contains that active ingr						
	producer, and is labeled for at least each use for						
labeled.	stoddesif and in innered for at teast each one to	miter my product is proposed to os					
(3) Indicate by checking (A) or (B) below which	h paragraph applics:						
X (A) An accurate Confidential Statement	of Formula (EPA FORM 8570-4) for the above	identified product is attached to this					
	indicates, by company name, registration numb	er, and product name, the source of the					
active ingredient(s) listed in paragra	aph (1)						
	OR						
(B) The Confidential Statement of Form	ula (CSF) (EPA Form 8750-4) referenced abov	e and on file with the EPA is complete.					
	he information required on the current CSF	, will divine the <u>D</u>					
(4) The following active ingredients in this production	luct avalify for the formulator's eventtion						
(7) The following delive ingledicins in this proc		····					
	Source						
Active Ingredient	Product Name	Registration Number					
-							
Permethrin							
	•						
Pyriproxyfen							
•							
1 1 ,	Name and Title	Date					
Canin tach	Vice President, Research & Development	August 3, 2012					
Signature Cray take							

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy Yellow - Applicant copy Virbac Effitix Plus 8/2/12

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named EFFITIXTM Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
TRANSMIT	TAL DOCUMENT	48896300
_ 1	Product Specific Chemistry For Effitix TM Plus Topical Solution for Dogs	48896301
2	Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxifen in Five Batches by Validated Methods	48896302
3	Determination of the physic-Chemical Property Appearance (Color, Physical State, and Odor) (D42327)	48896303
_ 4	Determination of Oxidation/reduction: Chemnical Incompatability (D42305)	48896304
5	Determination of the Physico-Chemical Property "Flash Point" (D42316)	48896305
, 6	Determination of the Physico-Chemical Property Viscosity (D42272)	48896306
7	Determination of the Physico-Chemical Property pH (D42294)	48896307
_ 8	Determination of the Physico-Chemical Property Relative Density (D42283)	48896308
V 9	Acute oral toxicity (D42171)	` 48896309
10	Acute dermal toxicity (D42182)	~ 48896310
11	Primary eye irritation (D42193)	34889631 I
12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix TM Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix TM Plus Topical Solution for Dogs	48896315

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIXTM PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil	6.0%
Permethin*	44.8%
Pyriproxyfen	1.8%
OTHER INGREDIENTS:	47.4%
TOTAL: to *cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans	00.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swaltowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. It signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

	FIRST AID
IF SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Cell a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency

medical treatment information or pesticide incidents.

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistant with its labelling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split lubes between dogs. Do not use multipla tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours efter the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

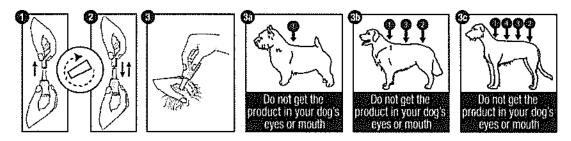
Do not apply more often than once a (per) month (every 30 days).

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of miles; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

- Ramove one applicator from packaging.
 - Hold applicator upright and remove cap.
- Invert cap and place other end back onto applicator tip.
 Push cap down to break seal.
 - Remove cap prior to treatment application.
- Part dog's hair until skin is visible.
 - Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX™ Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing] and lice in/estations can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are jalso] repelled by EFFITIXTM Plus Topical Solution for Dogs.

Fleas: EFFITIXTM Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and tasts for [up to) three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.

infestation is likely.

Ticks: EFFITIXTM Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIXTM Plus Topical Solution for Dogs can kill biting and chewing lice for jup toj a month. Apply monthly where lice control is consistently needed.

Mites: EFFITIXTM Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

Biting flies and Mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs [prevents blood (eeding by]]and] prepels biting flies and mosquitoes for up to 4 weeks [a (one] month]. Kills mosquitoes for up to four weeks [a [one] month].

Notes: Wait at least 30 days before re-application of EFFITIX^{TN} Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITEO WARRANTY AND OISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX[™] Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs f1 to 22.9 lbs (0.034 f1 oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 f1 oz)/(2.0 mL), targe dogs 45-88.9 lbs (0.135 f1 oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 f1 oz)/(6.0 mL).

Net Contents: f (3, 6 or 36] single-dose applicator(s] per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.0 f7 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (ot solution).

[Detachable] calendar (monthly application] reminder stickers (with illustration of dog or puppy]

Back Panel (single presentation on side panel) EPA Reg. No. 2382-xxx EPA Est. No. 2382-FRA-f

VIRBAC AH, INC. PO BOX 162059 FORT WORTH TX 76161 1-800-338-3659

Made in France
EFFITIX™ is a trademark of Virbac S.A.
Questions or comments? Calt: f-800-338-3659.

EPA Reg. No. 2382-xxx page 3 of 7 - Pending Master tabet Submitted August 3, 2012

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application See package insert for directions for use and storage and disposal See package insert for frequency of application and storage and disposal Open reseatable label for directions for use Open reseatable label for directions for use and storage and disposal See back panel for additional precautionary statements See package insert(s) for frequency of application See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use Lift here to open (LIFT HERE TO OPEN) For Use on Dogs ONLY Use ONLY on dogs See inside flap for directions for use

Text for Foil of Blister package

Virbac

EFFITIX™ Plus Topical Solution For Oogs

Only for use on dogs (4 to 10.9 lbs,11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-t32 lbs)/(0.017 oz ,0.034 fl oz,0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0mL)

Contains fipronit (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac
EFFITIX™ Plus
Topicat Solution For Dogs
Only for use on dogs
(4 to 10.9 lbs, 11 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/
(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (f (0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0mL))
Contains fipronil (6.0%), permethin (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions DO NOT USE ON CATS EPA Reg. No. 2382-xxx CAT PROHIBITION ICON

MARKETING CLAIMS

(Multiple infestations)

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When[Applied topically on a monthly basis, EFFITIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea larvae, [biting, chewing[lice, aids in the control of sarcoptic mites, and repels (and inhibits
 blood feeding by[biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFITIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea larvae, (biting, chewing (lice, aids in the control of mites that may cause sarcoptic mange,
 and repels land inhibits blood feeding by biting fles and mosquitoes.
- and repels [and inhibits blood feeding by[biting flies and mosquitoes.

 For easy and convenient application, EFFtTIXTM Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs (8 weeks old or older) and 4 to 10.9 lbs (0.17 fl oz([0.5 mL], small dogs 11 to 22.9 lbs [0.034 fl oz)[1.0 mL], medium dogs 23-44.9 lbs (0.068 fl oz([2.0mL], large dogs 45-88.9 lbs (0.135 fl oz([4.0 mL], and extra large dogs 89-132 lbs (0.203 fl oz([6.0 mL]))]
- j6.0 mLj.
 EFFITIXTM Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel (against) biting flies, and repel and kill mosquitoes.
- · Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- · Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, (and lice) infestations

- Research has shown that flea, flea egg, flea pupae, flea tarvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repetled by EFFITIXTM Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kilts fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long tasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIXTM Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain Idiscomfort) by controlling flea, flea egg, flea pupae, flea tarvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea aftergy dermatitis [FAD], or if reinfestation is
- Kills nawly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxylen to kill flea eggs and flea larvae
- With pyriproxyfen (IGR)* to break (the) flea life cycle *insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, (tularemia) [and tapeworm]
- Kills fleas [within 6 hours] that may transmit the following diseases; bartonellosis, (tularaemia) (and tapeworm infestations]
- Kills fleas lwithin 6 hours! that may transmit the following diseases; bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [Dipylidium caninum]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly]imitating] (annoying) (fleat bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermalitis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which (that) may causa flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea tarvae
- Kills adult fleas for up to one month (4 weeks)
- Prevents flea eggs from hatching or developing into larvae or adult stages (for up to [90 days) (3 months)]
- Kills adult fleas, flea eggs, and flea tarvae for up to three months (f2 weeks) however it your dog is susceptible to Flea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
 EFFtTIXTM Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Drice a month topical flea controt for dogs and pupples 8 weeks of age or older EFFtTIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea tarvae on dogs and puppies 6 weeks of age and older
- One application prevants further flea infastations for up to (12 weeks) (three months). Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment fall year) is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea tarvae
- Provides ongoing protection against fleas and the following diseases; bartonellosis, [tularemia][and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs)

 Treatment with EFFITIXTM Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea (prevention) [protection] year-round

[Ticks]

- Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for [up to[at least [one] month, Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks (that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis[
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks (that may transmit Rocky Mountain Spotted Fever], Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaptasmosis], American dog ticks (that may transmit Rocky Mountain Spotted Fever], and Brown dog ticks]that may transmit ehrlichiosis] for up to one month]4 weeks].
- Kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor veriabilis), Deet ticks (I/xodes spp) and Lone Star ticks [Ambtyomma americanum] for up to one month [4 weeks].
- Kills Lone Star ticks (Amblyomma americanum) for 4 weeks (for up to one month).
- Effective monthly application against ticks

(Mosquitoes and biting flies)

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks]]e (one] month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs [prevents blood feeding by] [and] (repels] biting flies and mosquitoes for [up to] 4 weeks (a]one] month]
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repals and kills mosquitoes often before they have a chance to take a blood meal
- ([Prevents blood-feeding by) [Kills and repels)] mosquitoes
- Repels biting flies
- Repels [(annoying][bothersome](nuisance]] biting flies
- Inhibits ||annoying|[bothersome |[nuisance]| biting flies
- ([Prevents](inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos [Cufex spp, Ochlerofafus spp, Aedes spp] which may vector heartworm [Dirofitaria immitis] for one month

[Lice and Mites]

- Lice: EFFI®X™ Plus Topical Solution for Dogs can kill biting and chewing lice for a Jone[month. Apply monthly where lice control is consistently needed.
- Mites: (EFFITIX[™] Plus Topicat Solution for Dogs] aids in]the] control of mites that may cause sarcoptic mange. Mites: (EFFITIX[™] Plus Topicat Solution for Dogs] aids in]the] control of sarcoptic mites
- EFF(TIXTM Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIXTM Plus Topical Solution for Dogs aids in (the) control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controts existing chewing/biting lice infestations
- Kills [(biting] (chewing]] lice
- For control and prevention of [[biting[[chewing]] lice [infestations]
- Stops existing ||biting||chewing|| lice infestations
- Prevents and controls [[biting]]chewing]] lice [infestations]
- Provides effective controt of [(biting] (chewing)] lice [infestations)
- Kills [(biting) [chewing]] lice and prevents further infestations
- For control and prevention of [infestation](with) [[biting] [chewing]] lice

[Others]

- t (3, 6, 36] applicator(s] (tube[s]) 0.5 mL (f.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- t (3, 6, 36] applicator(s] (tube|s)] 0.017 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- t (3, 6, 36) applicator(s) (tube)s) 0.017 floz]0.5 mL], (0.034 floz] 1.0 mL], 0.068 floz (2.0 mL), 0.135 floz (4.0 mL), 0.203
- t (3, 6, 36] applicator(s) (tube(s)) (each) containing 0.0 t7 fl oz (0.5mL) (0.034 fl oz] t.0 mL), 0.068 fl oz (2.0 mL), 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL)]
- t (3, 6, 36] applicator(s] (tube]s]]
- t (3, 6, 36] monthly dose(s] (application[s)]
- t (3, 6, 36] applicator(s] (tube(s)) 1 (3, 6, 36] month(ly) dose(s) (application(s)
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 1 t to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs]
- Easy and convenient application [applications]
- Remains effective for a (one) month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, (biting, chewing) lice and biting flies is prevented for a (one) month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply[spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topicat solution]

 EFFtTIX[™] Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or suntight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month] [for one month] [for up to four weeks[]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application See package insert for directions for use and storage and disposal See package insert for frequency of application and storage and disposal Open resealable labet for directions for use
Open resealable labet for directions for use and storage and disposal See back panet for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac

EFFITIXTM Plus Topical Solution For Dogs

Only for use on dogs (4 to 10.9 lbs, t1 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz ,0.034 fl oz,0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, f.0 mL, 2.0 mL, 4.0 mL, 6.0mL)

Contains fiprontl (6.0%), permethrin (44.88%), and pyriproxyfen (f.8%)

KEEP OUT OF REACH OF CHILOREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac
EFFIT(X™ Plus
Topical Solution For Dogs
Only for use on dogs
(4 to 10.9 lbs, 11 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/
(0.017 ft oz, 0.034 ft oz, 0.068 ft oz, 0.435 ft oz, 0.203 ft oz) [/ (0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)]
Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)

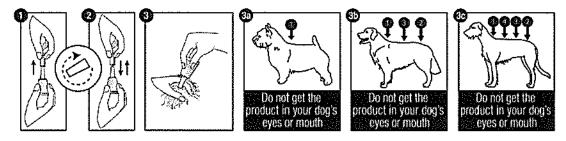
KEEP OUT OF REACH OF CHILDREN CAUTION
See full label for additional directions
DO NOT USE ON CATS
EPA Reg. No. 2382-XXX
CAT PROHIBITION (CON

MARKETING CLAIMS

[Multiple Infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [Winen] Applied topically on a monthly basis, EFFtTIX™ Plus Topical Solution for Dogs repels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea lervae, [biting, chewing] lice, aids in the control of sarcoptic mites, and repels (and inhibits
 blood feeding by) biting flies and mosquitoes.
- [When[Applied topically on a monthly basis, EFFtTIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of mites that may cause sarcoptic mange,
 and repels [and inhibits blood feeding by] biting flies and mosquitoes.
- and repels]and inhibits blood feeding by] biting flies and mosquitoes.

 For easy and convenient application, EFFITIXTM Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs (0.17 fl oz)(0.5 mL), small dogs 1 to 22.9 lbs [0.034 fl oz)(1.0 mL), medium dogs 23-44.9 lbs]0.068 fl oz] (2.0mL], large dogs 45-88.9 lbs]0.135 fl oz] (4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz) 16.0 mL].
- [6.0 mL]
 EFFITIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel jagainstj biting flies, and repel and kill mosquitoes.
- · Kills fleas, flea eggs, flea tarvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- · Repels and kills fleas and ticks
- · Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations



Insert

FREQUENCY OF APPLICATION

Fteas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing) and lice intestations can be controlled with monthly applications of EFFITIX™ Plus Topical Solution for Dogs. Biting flies and mosquitoes are (also] repelled by EFFITIX™ Plus Topical Solution for Dogs.

Fleas: EFFITIXTM Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for Jup to three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if rein/estation is likely.
Ticks: EFFITIXTM Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently

needed.

Lice: EFFITIXTM Plus Topical Solution for Dogs can kill biting and chewing lice for (up to [a month. Appty monthly where lice control

is consistently needed.

Mites: EFFITIXTM Plus Topical Solution for Dogs aids in [the] control of [sarcoptic mange]/[mite infestations that may cause sarcoptic

Bitting files and Mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs [prevents blood feeding by] (and] (repels) billing flies and mosquitoes for up to 4 weeks (a [one[month). Kills mosquitoes for up to four weeks [a [one[month].

Notes: Wait at least 30 days before re-application of EFFITIXTM Plus Topical Solution for Oogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposel.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable, Do not reuse or refill this container, Offer for recycling, if available, If partiatty fitted: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND OISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIXTM Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 cz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl cz)/(1.0 mL), medium dogs 23-44,9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (fmL, 2mL, 4mL or 6mL)/ 0.017 ft oz, (0.034 ft oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

[Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy]

Back Panel (single presentation on side panel) EPA Reg. No. 2382-xxx EPA Est. No. 2382-FRA-1

VIRBAC AH, INC. PO BOX 162059 FORT WORTH TX 76161 1-800-338-3659

Made in France EFFITIX[™] is a trademark of Virbac S.A. Questions or comments? Call: 1-800-338-3659.

EPA Reg. No. 2382-xxx page 3 of 7 - Pending Master label Submitted August 3, 2012

Back Panel (single presentation on insert)

	FIRST AID
tF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice.
	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to do so by a poison control center or doctor.
	Do not give anything to an unconscious person.
tF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	Take off contaminated clothing.
	Rinse skin immediately with plenty of water for 15-20 minutes.
	Cell a poison control center or doctor for treetment advice.

Have product container or labet with you when calting a poison control center or doctor, or going for treatment.

You may also contact the Hottine number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its lebelling. On not allow children to appty product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE, FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY, DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Oo not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flee and tick control product.

Do not apply more often than once a [per] month [every 30 days].

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

- Remove one applicator from packaging.
 - Hold applicator upright and remove cap.
- Invert cap and place other end back onto applicator tip.
 Push cap down to break seal.
 - Push cap down to break seal.
- Remove cap prior to treatment application.
- Part dog's hair until skin is visible.
 - Place applicator tip directly against exposed skin.
- 3a. For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 tbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra targe dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITIX[™] Plus Topical Solution for Dogs is not applied superficially on dog's hair.

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIXTM PLUS TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil	6.0%
Fipronil	44.8%
Pyńproxyfen	
OTHER INGREDIENTS:	47.4%
TOTAL: * cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans	. 100.0%

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZAROS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZAROS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on pupples under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are Jalsoj repelled by EFFITIXTM Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIXTM Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lica on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and tice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or if reinfestation is
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIX™ Plus Topical Solution
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen (IGR)* to break [the] flea life cycle *insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia[[and tapeworm]
- Kills fleas within 6 hours that may transmit the following diseases: bartonellosis, [tularaemia] [and tapeworm infestations]
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [Dipylidium caninum]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas within 6 hours] that may cause Flea Allergy Dermatitis (FAD)]or) [flea-bite anemia]
- Fteas do not have to bite to die
- Controls highly [irritating] (annoying] [flea) bites
- EFFITIXTM Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermatitis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days]]3 months])
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
 EFFITIXTM Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea tarvae
- Provides ongoing protection against fleas and tha following diseases; bartonellosis, Itularemia]]and tapeworm infestations(they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea tarvae
- Prevents |Stops) re-infestations by killing adult fleas (before they lay eggs)
 Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis |FAD| or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea (prevention) [protection] year-round

[Ticks]

- Ticks: EFFITIXTM Plus Topical Solution for Dogs can kill ticks for (up to[at least [one] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks [that may transmit ehrlichiosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], and Brown dog ticks [that may transmit ehrlichiosis] for up to one month [4 weeks].
- Kills Brown dog ticks [Rhipicephatus spp], American dog ticks [Dermacentor variabilis], Deer ticks [Ixodes spp] and Lone Starticks (Amblyomma americanum] for up to one month [4 weeks].
- Kills Lone Star ticks (Amblyomma americanum) for 4 weeks [for up to one month].
- Effective monthly application against ticks

[Mosquitoes and biting flies(

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a [one] month]
- · Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs [prevents blood feeding by)
 [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a [one] month]
- Repels and kills mosquitoes for up to four [4] weeks
- · Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- · Repels and kills mosquitoes often before they have a chance to take a blood meal
- ||Prevents blood-feeding by) [Kills and repels|| mosquitoes
- · Repels biting flies
- Repels ([annoying[[bothersome][nuisance]] biting flies
- Inhibits ((annoying)|bothersome ||nuisance|) biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos (Culex spp, Ochlerofafus spp, Aedes spp) which may vector heartworm |Dirofilaria immitis| for one month

(Lice and Mites (

- Lice: EFFITIX™ Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIXTM Plus Topical Solution for Dogs] aids in [the] control of mites that may cause sercoptic mange.
- Mites: [EFFITIXTM Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites
- EFFITIXTM Plus Topical Solution for Dogs aids in (the) controt of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIXTM Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in [the] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- . [Also] Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in controt of sarcoptic mites
- Controls existing chewing/biting lice in/estations
- Kills [[biting] (chewing)] lice
- For control and prevention of ||bifing| |chewing|| lice |in/estations)
- Stops existing ([biting) (chewing)) lice infestations
- Prevents and controls ([biting] [chewing]) lice [infestations)
- Provides effective control of [[biting] [chewing]] lice [infestations]
- · Kills ||biting) (chewing|| lice and prevents further infestations
- For control and prevention of [infestation][with] [[biting] [chewing]] lice

(Others(

- t (3, 6, 36) applicator(s) (tube(s)) 0.5 mL (t.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.0 t7 fl oz |0.5 mL), (0.034 fl oz (f.0 mL), 0.068 fl oz [2.0 mL), 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL))
- 1 (3, 6, 36) applicator(s) (tube[s]) (each) containing 0.017 fl oz (0.5mL((0.034 fl oz (1.0 mL), 0.068 fl oz (2.0 mL), 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL))
- 1 (3, 6, 36) applicator(s) (tube(s))
- 1 (3, 6, 36) monthly dose(s) (application(s))
- t (3, 6, 36) applicator(s) (tube(s)) 1 (3, 6, 36) month(ly) dose(s) (application(s)
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs]
- Easy and convenient application (applications)
- Remains effective for a [one] month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquiloes and biting flies
- Slops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, licks and mosquiloes, [biting, chewing] lice and biting flies is prevented for a (one) month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use[Easy] to apply] spot-on [topical] application
- Fragrance (odor) free
- No noticeable odors
- Single application lasts 4 weeks Jone month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical sotution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [tn] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]

 EFFtTIXTM Plus Topicat Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight
- Waterproof (remains effective after bathing and swimming) for up to four weeks]a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month] [for one month] [for up to four weeks]]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package [applicator tubes]

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIXTM **PLUS** TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil	6.0%
Permethrin*	44.8%
Pyńproxyfen	
OTHER INGREDIENTS:	
TOTAL: * cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans	

KEEP OUT OF REACH OF CHILDREN CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panelf Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATEO OOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panet

Do not use on puppies under 8 weeks of age, individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and finse with targe amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animats known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

	FIRST AIO
IF SWALLOWED:	Call a poison controt center or doctor immediately for treatment advice.
	Have person sip a glass of water if able to swallow.
	Oo not induce vomiting unless told to do so by a poison control center or doctor.
	Oo not give anything to an unconscious person.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	Call a poison controt center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	Take off contaminated clothing.
	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.

Have product container or label with you when calting a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.

thside flap (single presentation insert only)

OIRECTIONS FOR USE

tt is a violation of Federal law to use this product in any manner inconsistent with its labelling. Do not allow children to apply product, TO PREVENT HARM TO YOU AND YOUR DOG, REAO ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY, DO NOT USE ON CATS OR RABBITS, DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks ot age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. It your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

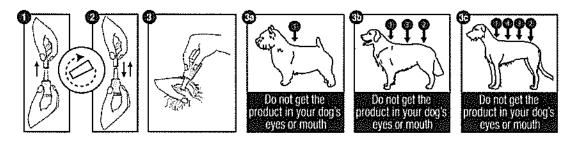
Do not apply more often than once a (per) month [every 30 days].

For use on DOGS and PUPPtES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use

APPLICATION DIRECTIONS

- Remove one applicator from packaging. Hold applicator upright and remove cap.
- 2.
- Inverticap and place other end back onto applicator tip. Push cap down to break seal.
 - Remove cap prior to treatment application.
- 3. Part dog's hair until skin is visible.
 - Place applicator tip directly against exposed skin.
- For small dogs and puppies 8 weeks old or older weighing 4 to 10.9 lbs or weighing t1 to 22.9 lbs- Deposit 3e, entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- For medium dogs 23-44.9 lbs or targe dogs 45-88.9 lbs- Apply the product eventy to three spots on the dog's back, 3b. starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- For extra targe dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the 3c. shoulder blades and continuing on to the second, third and fourth spots as shown in diegram 3c, squeezing the applicator until empty.

Ensure that EFFITIX^{FM} Plus Topical Solution for Dogs is not applied superficielly on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biling and chewing) and lice intestations can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are (also] repelled by EFFITIXTM Plus Topical Solution for

Fleas: EFFITIXTM Plus Topical Solution for Oogs can start killing adult fleas within 6 hours and lasts for (up to) three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-

Infestation is likely.

Ticks: EFFITIX™ Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently

Lice: EFFITIXTM Plus Topical Solution for Dogs can kill biting and chewing lice for Jup to a month. Apply monthly where lice control

is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in (the] control of]sarcoptic mange)f[mite infestations that may cause sarcoptic

Biting flies and Mosquitoes: When applied monthly, EFFITIX™ Plus Topical Solution for Dogs (prevents blood feeding by)]and] prepels biting flies and mosquitoes for up to 4 weeks (a (one) month). Kills mosquitoes for up to four weeks (a (one) month).

Notes; Wait at least 30 days before re-application of EFFITIXTM Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container, Offer for recycling, if available. If partially filted: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFtTIXTM Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fi oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.058 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (tmL, 2mL, 4mL or 6mL)f 0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0, f35 fl oz, 0.203 fl oz) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy)

Back Panel (single presentation on side panel) EPA Reg. No. 2382-xxx EPA Est No. 2382-FRA-1

VIRBAC AH, INC. PO BOX 162059 FORT WORTH TX 76161 1-800-338-3659

Made in France EFFITIX™ is a trademark of Virbac S.A. Questions or comments? Call: 1-800-338-3659.

EPA Reg. No. 2382-xxx page 3 of 7 - Pending Master label Submitted August 3, 2012

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application. See package insert for directions for use and storage and disposal. See package insert for frequency of application and storage and disposal. Open resealable label for directions for use. Open resealable tabel for directions for use and storage and disposal. See back panel for additional precautionary statements. See package insert(s) for frequency of application. See enclosed insert(s) for directions for use and storage and disposal. See enclosed insert(s) for directions for use. Lift here to open (LIFT HERE TO OPEN). For Use on Dogs ONLY. Use ONLY on dogs. See inside flap for directions for use.

Text for Foil of Blister package

Virbac

EFFITtXTM Plus Topical Solution For Dogs

Only for use on dogs (4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz ,0.034 fl oz,0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

OO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac
EFFITIX^{FM} Plus
Topicat Solution For Dogs
Only for use on dogs
(4 to 10.9 lbs, 11 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)f
(0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) [/ (0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0mL)]
Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions DO NOT USE ON CATS EPA Reg. No. 2382-xxx CAT PROHIBITION ICON

MARKETING CLAIMS

[Multiple Infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea tarvae, ticks, mosquitoes, and lice.
- [When] Applied topically on a monthly basis, EFFtTIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of sarcoptic mites, and repels and inhibits
 blood feeding by) biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFFtTIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, [biting, chewing] lice, aids in the control of mites that may cause sarcoptic mange, and repels (and inhibits blood feeding by[biting flies and mosquitoes.
 For easy and convenient application, EFFITIXTM Plus Topical Solution for Dogs is available in sizes for puppyltoy dogs]8
- For easy and convenient application, EFFITIX^{IIII} Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs [0.17 fl oz][0.5 mL], small dogs 11 to 22.9 lbs (0.034 fl oz][1.0 mL), medium dogs 23-44.9 lbs [0.068 fl oz) (2.0mL], large dogs 45-88.9 lbs [0.135 fl oz) [4.0 mL], and extra large dogs 89-132 lbs (0.203 fl oz) [6.0 mL].
- [6,0 mL].
 EFFITIXTM Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel Jagainst) biting flies, and repel and kill mosquitoes.
- · Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, biting flies and mosquitoes
- Kills and repels ticks
- · For the control and prevention of flea, flea egg, flea pupae, flea larvae, (and lice] infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are Jalso] repelled by EFFITIXTM Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea tarvae, tick and mosquito controt for your pet EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and controt of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and tice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain (discomfort) by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAO), or if reinfestation is
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIXTM Plus Topical Solution
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills [adult] fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea tarvae
- With pyriproxyfen (IGR)* to break (the) flea life cycle *insect growth regulator
- Kills fleas (within 6 hours) that may transmit bartonellosis, (tularemia) (and tapeworm)
- Kills fleas (within 6 hours) that may transmit the following diseases: bartonellosis, [tutaraemia] (and tapeworm infestations)
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tutaremia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms (Dipylidium caninum)
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may cause Flea Allergy Dermatitis (FAD) for) [flea-bite anemia]
- Fleas do not have to bite to die
- Controls_highly (irritating) (annoying) [flea] bites
- EFFITIXTM Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD [Flea Allergy Dermatitis]
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]

 EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [12 weeks] however if your dog is susceptible to Flea Altergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae
 EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and puppies 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [t2 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment [all year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides angoing protection against fleas and the following diseases: bartonellosis [tutaremia]]and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents (Stops) re-infestations by killing adult fleas [before they lay eggs)
- Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis (FAD) or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea (prevention) (protection) year-round

(Ticks)

- Ticks: EFFtTIX™ Plus Topical Solution for Dogs can kill ticks for (up to) at least Jone] month. Apply monthly where tick control is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis]
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks [that may transmit ehrlichlosis], and Lone Star ticks [that may transmit hepatozoonosis] for up to one month [4 weeks)
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever], and Brown dog ticks (that may trensmit ehrlichlosis (for up to one month (4 weeks).
- Kills Brown dog ticks [Rhipicephalus spp], American dog ticks [Dermacenfor variabilis], Deer ticks [Ixodes spp] and Lone Star ticks [Amblyomma americanum] for up to one month [4 weeks].
- Kills Lone Star ticks (Amblyomma americanum) for 4 weeks [for up to one month].
- Effective monthly application against ticks

(Mosquitoes and biting flies)

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a [one[month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting files and mosquitoes: When applied monthly, EFFITIXTM Ptus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to] 4 weeks [a [one] month]
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits] blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
-]] Prevents blood-feeding by] (Kills and repels]) mosquitoes
- Repels biting flies
- Repels [[annoying][bothersome][nuisance]] biting flies
- Inhibits [[annoying][bothersome][nuisance]] biting flies
- [[Prevents][inhibits][blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repets and kills mosquitos (Culex spp, Ochlerofatus spp, Aedes spp(which may vector heartworm |Dirofilaria immitis) for one month

(Lice and Mites)

- Lice: EFF!T(XTM Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIXTM Ptus Topical Solution for Dogs] aids in [the] control of mites that may cause sarcoptic mange.
- Mites: |EFFITIX™ Ptus Topical Solution for Dogs) aids in [the] control of sarcoptic mites
- EFFITIXTM Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange. [When applied monthly], EFFITIXTM Plus Topical Solution for Dogs aids in [the] control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite infestation
- Kills chewing and biting lice
- JAIso[Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills [[biting]]chewing]) lice
- For control and prevention of [[biting] [chewing)[lice [infestations]
- Stops existing [[biting]]chewing]] lice infestations
- Prevents and controls [(biting) (chewing)] lice (infestations)
- Provides effective control of [[biting[[chewing]] lice [infestations[
- Kills [[biting]]chewing]] lice and prevents further infestations
- For control and prevention of [infestation][with)](biting) (chewing]] lice

(Others (

- 1 (3, 6, 36) applicator(s) (tube(s)) 0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- 1 [3, 6, 36] applicator[s] [tube[s]) 0.017 fl oz [0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator[s] [tube[s]) 0.017 fl oz [0.5 mL], (0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL), 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL])
- t (3, 6, 36) applicator(s) [tube(st) [each] containing 0.017 fl oz [0.5mL] [0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz]4.0 mL[, 0.203 fl oz [6.0 mL])
- 1 [3, 6, 36) applicator(s) (tube(s))
- 1 (3, 6, 36) monthly dose(s) (application[s])
- 1 [3, 6, 36) applicator(s) (tube(s)) f (3, 6, 36) month(ly) dose(s) (application(s)
- DO NOT USE ON CATS
- This product is only for use on dogs and pupples 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application (applications)
- Remains effective for a [one] month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing in/estations and prevents establishment of new infestations for fleas and ticks
- Reintestation of fleas, ticks and mosquitoes, [biting, chewing] lice and biting flies is prevented for a Jone] month

- Convenient topical treatment for dogs
- · Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-]infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply[spot-on [topical[application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks Jone month[[30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical sotution
- · Starts working by [on[contact
- In child-resistent packaging
- Convenient [to use], easy to apply [topical solution]
- EFFITIX[™] Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- · Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- · Maintains residuel efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month] [for one month] [for up to four weeks][
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- · For dogs that enjoy the outdoors
- · Sold by veterinarians
- · Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- · Illustration of mosquito
- tlustration of mite
- tllustration of louse
- Picture or illustration of a dog [or puppy]
- · Picture or illustration of the Virbac logo
- · Picture or illustration of the primary package [applicator tubes]

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIXTM **PLUS** TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil	6.0%
Permethrin*	4.8%
Pyriproxyfen	1.8%
OTHER INGREDIENTS:	7.4%
TOTAL:	0.0%
* cis/trans ratio: maximum 55% (±) cis and minimum 45% (±) trans	

CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS – IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary inflation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

	FIRST AID
IF \$WALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.
IF IN EYES;	 Hold eye open and rinse slowly and gently with water for t5-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING :	 Take off contaminated clothing. Rinse skin immediately with plenty of water for f5-20 minutes. Call a poison control center or doctor for treatment advice.

Have product container or label with you when calling a poison control center or doctor, or going for treatment.

You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or posticide incidents.

Inside flap (single presentation insert only)

DIRECTIONS FOR USE

tt is a violation of Federal law to use this product in any manner inconsistent with its lebelling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE, FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY, DO NOT USE ON CATS OR RABBITS, DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPLES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

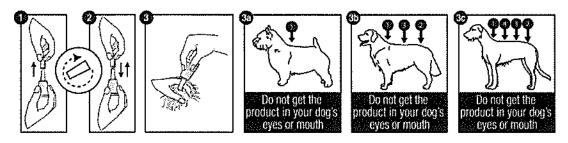
Do not apply more often than once a [per] month [every 30 days].

For use on DOGS and PUPPIES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kilt flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

- t. Remove one applicator from packaging.
 - Hold applicator upright and remove cap.
- Invert cap and place other end back onto applicator tip. Push cap down to break seal.
 - Remove cap prior to treatment application.
- Part dog's hair until skin is visible.
 - Place applicator tip directly against exposed skin.
- 3a. For small dogs and pupples 8 weeks old or older weighing 4 to f0.9 lbs or weighing ff to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onlo dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 the or large dogs 45-88.9 lbs- Apply the product eventy to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFITiX™ Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, (biting and chewing) and lice infestations can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are [also] repelled by EFFITIXTM Plus Topical Solution for Dogs.

Fleas: EFFITIX™ Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for Jup to] three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAO), or if reinfestation is likely

infestation is likely.

Ticks: EFFITIXTM Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIXTM Plus Topical Solution for Oogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed

is consistently needed.

Mites: EFFITIX™ Plus Topical Solution for Dogs aids in (the) control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

Bitting flies and Mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs Iprevents blood feeding by) [and] (repels[biting flies and mosquitoes for up to 4 weeks [a (one) month). Kills mosquitoes for up to four weeks [a (one) month).

Notes; Wail at least 30 days before re-application of EFFIT!XTM Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panet (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND OISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX[™] Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs 11 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 lbs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-t32 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mL or 6mL)/ 0.017 fl oz, (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

[Oetachable] calendar (monthly application) reminder slickers (with illustration of dog or puppy]

Back Panel (single presentation on side panel) EPA Reg. No. 2382-xxx EPA EsL No. 2382-FRA-1

VIRBAC AH, INC. PO BOX 162059 FORT WORTH TX 76161 1-800-338-3659

Made in France EFFITIX[™] is a trademark of Virbac S.A. Questions or comments? Call: 1-800-338-3659.

EPA Reg. No. 2382-xxx page 3 of 7 - Pending Master label Submitted August 3, 2012

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert(s) for directions for use and frequency of application See package insert for directions for use and storage and disposal See package insert for frequency of application and storage and disposal Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert(s) for directions for use and storage and disposal
See enclosed insert(s) for directions for use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac

EFFITIXTM Plus Topical Solution For Dogs

Only for use on dogs (4 to 10.9 lbs, f1 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz ,0.034 fl oz,0.068 fl oz, 0.135 fl oz, 0.203 fl oz) (0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0mL)

Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

EPA Reg. No. 2382-xxx

DO NOT USE ON CATS

CAT PROHIBITION ICON

Text for Applicator Tube

Virbac

EFFtTIX[™] Plus
Topical Solution For Dogs
Only for use on dogs
(4 to 10.9 lbs, f1 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/
(0.017 floz, 0.034 floz, 0.068 floz, 0.135 floz, 0.203 floz) (/ (0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL))
Contains fipronil (6.0%), permethán (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions DO NOT USE ON CATS EPA Reg. No. 2382-xxx CAT PROHIBITION ICON

MARKETING CLAIMS

[Muttiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- (When) Applied topically on a monthly basis, EFFtTIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea larvae, (biting, chewing) lice, aids in the control of sarcoptic mites, and repels [and inhibits
 blood feeding by] biting flies and mosquitoes.
- [When] Applied topically on a monthly basis, EFF(TIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea larvae, (biting, chewing) flice, aids in the control of mites that may cause sercoptic mange, and repels (and inhibits blood feeding by biting flies and mosquitoes.
 For easy and convenient application, EFFIT(XTM Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8]
- For easy and convenient application, EFFITIX[™] Plus Topicat Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs [0.17 fi oz]]0.5 mL], small dogs 11 to 22.9 lbs (0.034 fi oz) t.0 mL), medium dogs 23-44.9 lbs [0.068 fi oz] [2.0mL], large dogs 45-88.9 lbs [0.135 fi oz] [4.0 mL], and extra large dogs 89-132 lbs (0.203 fi oz) 16.0 mL1.
- [6.0 mL].
 EFFtTIX™ Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ticks and lice; repel]against) biting flies, and repel and kill mosquitoes.
- . Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- · Repels and kills flaas and ticks
- · Repels fleas, ficks, biting flies and mosquitoes
- Kills and repels ticks
- For the control and prevention of flea, flea egg, flea pupae, flea larvae, (and lice) infestations

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) tice infestations, can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are (also) repelled by EFFtTIXTM Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea tarvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFFITIXTM Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to retieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in confrol of sarcoptic mites
- Kills fleas, flea eggs, flea larvae, ticks, mosquitoes, lice, and aids in control of mites that may cause sarcoptic mange
- Kills and repels fleas, ticks, and mosquitoes.

)Fteas)

- Fleas: EFFtĭtX™ Plus Topical Solution for Dogs can kill edult fleas in 6 hours end adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFFITIXTM Plus Topical Solution for Doas
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills (adult) fleas
- Prevents all flea stages (adult fleas, flea eggs, flea pupae and flea larvae)
- Prevents development of all flea stages (flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Duat Action: fipronil and permethnin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxylen (IGR)* to break [the] flea life cycle *insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas within 6 hours that may transmit the following diseases: bartonellosis, [tularaemia] land tapeworm infestations]
- Kills fleas |within 6 hours| that may transmit the following diseases: bartonellosis and tutaremia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediata host for tapeworms [Dipylidium caninum]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills (adult) fleas (within 6 hours) that may causa Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia]
- Fleas do not have to bite to die
- Controls highly [irritating] [annoying] [flea] bites
- EFFITIXTM Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermafitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis [FAD]
- EFFITIX™ Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea larvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to [90 days] [3 months]]
- Kills adult fleas, flea eggs, and flea larvae for up to three months [f2 weeks] however if your dog is susceptible to Ftea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae EFFITtXTM Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea larvae on your dog
- Once a month topical flea control for dogs and pupples 8 weeks of age or older
- EFFITIXTM Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment (all year) is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea tarvae
- Provides ongoing protection against fleas and the following diseases: bartonellosis,[tutaremia][and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea tarvae
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs]

 Treatment with EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea (prevention)) protection[year-round

[Ticks]

- Ticks: EFFtTIX™ Plus Topical Solution for Dogs can kill ticks for [up to[at least [one] month. Apply monthly where tick control is consistently needed.
- Kills and recels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis[
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichlosis), and Lone Star ticks (that may transmit hepatozoonosis) for up to one month (4 weeks)
- Kills ticks including Deer ticks (that may transmit Lyme disease and aneplesmosis), American dog ticks (that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks [that may transmit ehrlichiosis[for up to one month [4 weeks].
- Kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor variabilis), Deer ticks (Ixodes spp) and Lone Star ticks (Amblyomma americanum) for up to one month [4 weeks].
- Kills Lone Star ticks (Amblyomma americanum) for 4 weeks (for up to one month).
- Effective monthly application against ticks

(Mosquitoes and biting flies)

- Kills mosquitoes
- Kills mosquitoes for up to 28 days [four weeks] [a [one] month]
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs (prevents blood feeding by [and] (repels] biting flies and mosquitoes for [up to] 4 weeks (a (one) month)
- Repels and kills mosquitoes for up to four (4) weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents (inhibits) blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] (Kills and repels]) mosquitoes
- Repels biting flies
- Repels ([annoying][bothersome][nuisance][biting flies
- Inhibits ((annoying[[bothersome][nuisance]) biting flies
- [[Prevents[[inhibits[] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos (Culex spp, Ochlerotatus spp, Aedes spp) which may vector heertworm [Dirofilana immitis] for one month

(Lice and Mites)

- Lice: EFF1TIXTM Plus Topical Solution for Dogs can kill biting and chewing lice for a [one] month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIXTM Plus Topical Solution for Dogs) aids in [the[control of mites that may cause sarcoptic mange.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs] aids in [the[control of sarcoptic mites
- EFFITIXTM Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange. [When applied monthly], EFF\TIXTM Plus Topical Solution for Dogs aids in (the) control of sarcoptic mange.
- Aids in (the) control of sarcoptic mange mite in/estation
- Kills chewing and biting lice
- (Also) Kills lice and aids in control of mites that may cause sarcoptic mange
- (Also] Kills lice and aids in control of sarcoptic mites
- Controls existing chewing/biting lice infestations
- Kills ([biting] [chewing]] lice
- For control and prevention of ((biting) (chewing[[lice [infestations]
- Stops existing [(biting) [chewing)] lice infestations
- Prevents and controls [(biting) (chewing)) lice [infestations)
- Provides effective control of ([biting) [chewing]) lice (infestations)
- Kills [[biting] (chewing)] lice and prevents further infestations
- For control and prevention of (infestation)(with) [[biting[[chewing]] lice

(Others)

- t (3, 6, 36) applicator(s) (tube(s[) 0.5 mL (t.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- t (3, 6, 36) applicator(s) (tube(st) 0.0 t7 fl oz (0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator(s) (tube(s)) 0.017 fl oz [0.5 mL), (0.034 fl oz (1.0 mL), 0.068 fl oz [2.0 mL], 0.135 fl oz [4.0 mL), 0.203 fl oz [6.0 mL])
- 1 (3, 6, 36) applicator(s) (tube[s]) (each) containing 0.0 t7 fl oz [0.5mL] (0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz (4.0 mL), 0.203 fl oz (6.0 mL)
- 1 (3, 6, 36) applicator(s) (tube(s))
- 1 (3, 6, 36) monthly dose(s) (application(s))
- 1 (3, 6, 36) applicator(s) (tube(s)) 1 (3, 6, 36) month(ly) dose(s) (application(s)
- DO NOT USE ON CATS
- This product is only for use on dogs and pupples 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 1 f to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application [applications]
- Remains effective for a (one) month [4 weeks) tor fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops existing infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, [biting, chewing) lice and biting flies is prevented for a [one[month

- Convenient topical treetment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents [re-linfestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] [to use] Easy [to apply[spot-on [topical] application
- Fragrance [odor] free
- No noticeable odors
- Single application lasts 4 weeks [one month] [30 days[
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] confact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]

 EFF(TIXTM Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- "Waterproof [remains effective after bathing and swimming] for up to four weeks [a month] [one month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residual efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [[for a month] [for one month] [for up to four weeks]]
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac logo
- Picture or illustration of the primary package (applicator tubes)

Virbac's Master Label

Date 19 July 2012 Version US-19 EPA Reg. No. 2382-xxx Fipronil+Permethrin+Pyriproxyfen Topical Solution for Dogs

Optional Text Appears In Brackets

EFFITIXTM **PLUS** TOPICAL SOLUTION FOR DOGS

Front, back and side panels

FOR USE ONLY ON DOGS AND PUPPIES 8 WEEKS OLD OR OLDER (WEIGHING 4 TO 10.9 LBS, WEIGHING 11 TO 22.9 LBS, WEIGHING 23 TO 44.9 LBS, WEIGHING 45 TO 88.9 LBS, WEIGHING 89 TO 132 LBS).

Front panel and Back Panel

ACTIVE INGREDIENTS:

Fipronil	6.0%
permethrin*	44.8%
Pyriproxyfen	
OTHER INGREDIENTS:	47.4%
TOTAL: * cis/trans ralio: maximum 55% (±) cis and minimum 45% (±) trans	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

READ ENTIRE LABEL BEFORE EACH USE

Back Panel

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

Harmful if swallowed or absorbed through the skin. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY.

Symbol on Front Panel/ Symbol and text on Back panel



DO NOT USE ON CATS - IF INGESTED BY CAT THAT ACTIVELY GROOMS A RECENTLY TREATED DOG, THIS PRODUCT MAY HAVE SERIOUS HARMFUL EFFECTS. IF THIS OCCURS, CONTACT YOUR VETERINARIAN IMMEDIATELY.

Back Panel

Do not use on puppies under 8 weeks of age, Individual sensitivities, while rare, may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or animals known to be sensitive to pesticide products.

Back Panel (single presentation on insert)

	FtRST AtO
IF SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to do so by a poison control center or doctor.
	Do not give anything to an unconscious person.
tF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
	Call a poison control center or doctor for treatment advice.
IF ON SKIN OR	Take off contaminated clothing.
CLOTHING:	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.

Have product container or label with you when calting a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-338-3659 for human or veterinary health concerns, emergency medical treatment information or pesticide incidents.

Inside flap (single presentation Insert only)

OIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labelling. Do not allow children to apply product, TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS, DO NOT USE ON OTHER ANIMALS.

OO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs and puppies under 8 weeks of age. Do not split tubes between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flee and tick control product.

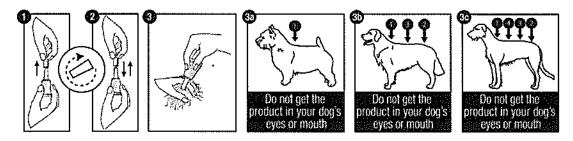
On not apply more often than once a [per) month (every 30 days].

For use on DOGS and PUPPtES 8 weeks old or older. To repel and kill fleas, ticks, and mosquitoes; to kill flea eggs, pupae and larvae, lice, and to aid in control of mites; to repel and prevent blood feeding by biting flies. Apply monthly according to directions for use.

APPLICATION DIRECTIONS

- Remove one applicator from packaging.
 - Hold applicator upright and remove cap.
- Inverticap and place other end back onto applicator tip. Push cap down to break seal.
 - Remove cap prior to treatment application.
- 3. Part dog's hair until skin is visible.
 - Place applicator tip directly against exposed skin.
- 3a. For small dogs and pupples 8 weeks old or older weighing 4 to 10.9 lbs or weighing 11 to 22.9 lbs- Deposit entire contents by squeezing the entire applicator contents onlo dog's skin, at a single site, between the shoulder blades as shown in diagram 3a.
- 3b. For medium dogs 23-44.9 lbs or large dogs 45-88.9 lbs- Apply the product eventy to three spots on the dog's back, sterting between the shoulder blades and continuing on to the second and third spots as shown in diagram 3b, squeezing the applicator until empty.
- 3c. For extra large dogs 89-132 lbs- Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots as shown in diagram 3c, squeezing the applicator until empty.

Ensure that EFFtTIXTM Plus Topical Solution for Dogs is not applied superficially on dog's hair.



Insert

FREQUENCY OF APPLICATION

Fleas, flea eggs, flea pupae, flea larvae, ticks, [biting and chewing(and lice infestations can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biling flies and mosquitoes are [also] repelled by EFFITIXTM Plus Topical Solution for Dogs.

Fleas: EFFITIXTM Plus Topical Solution for Dogs can start killing adult fleas within 6 hours and lasts for (up to) three months against adult fleas, flea eggs and flea larvae. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfectation is likely

infestation is likely.

Ticks: EFFITIXTM Plus Topical Solution for Dogs can kill ticks for at least a month. Apply monthly where tick control is consistently needed.

Lice: EFFITIXTM Plus Topical Solution for Dogs can kill biting and chewing lice for [up to] a month. Apply monthly where lice control is consistently needed.

is consistently needed.

Mites: EFFITIXTM Plus Topical Solution for Dogs aids in [the[control of [sarcoptic mange]/[mite infestations that may cause sarcoptic mange].

Biting files and Mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs (prevents blood feeding by) (and(prepets) biting flies and mosquitoes for up to 4 weeks (a (one) month). Kills mosquitoes for up to four weeks [a pone] month].

Notes: Wait at least 30 days before re-application of EFFITIX[™] Plus Topical Solution for Dogs. Avoid contact with treated area until dry.

Back Panel (single presentation on insert)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE: Store unused product in original container only, out of reach of children and animals.

PESTICIDE /CONTAINER DISPOSAL: If empty: Nonrefillable. Do not reuse or refill this container. Offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Inside Flap (single presentation on insert)

LIMITED WARRANTY AND DISCLAIMER

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.

How supplied: For easy and convenient application, EFFITIX[™] Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs 8 weeks old or older and 4 to 10.9 lbs (0.017 oz)/(0.5 mL), small dogs t1 to 22.9 lbs (0.034 fl oz)/(1.0 mL), medium dogs 23-44.9 [bs (0.068 fl oz)/(2.0 mL), large dogs 45-88.9 lbs (0.135 fl oz)/(4.0 mL), and extra large dogs 89-132 lbs (0.203 fl oz)/(6.0 mL).

Net Contents: 1 (3, 6 or 36) single-dose applicator(s) per package containing 0.5 mL, (1mL, 2mL, 4mt, or 6mL)/ 0.017 fl oz, (0.034 fl oz, 0.058 fl oz, 0.135 fl oz, 0.203 fl oz) (of solution).

(Detachable) calendar (monthly application) reminder stickers (with illustration of dog or puppy(

Back Panel (single presentation on side panel) EPA Reg. No. 2382-xxx EPA Est. No. 2382-FRA-1

VIRBAC AH, INC. PO BOX f62059 FORT WORTH TX 7616 f 1-800-338-3659

Made in France EFFITIX[™] is a trademerk of Virbac S.A. Questions or comments? Call: 1-800-338-3659.

EPA Reg. No. 2382-xxx page 3 of 7 - Pending Master label Submitted August 3, 2012

Text for Front Panel, Back Panel, Inside Flap and Side Panel

See package insert[s) for directions for use and frequency of application See package insert for directions for use and storage and disposal See package insert for frequency of application and storage and disposal Open resealable label for directions for use
Open resealable label for directions for use and storage and disposal See back panel for additional precautionary statements
See package insert(s) for frequency of application
See enclosed insert[s) for directions for use and storage and disposal
See enclosed insert[s) for directions tor use
Lift here to open (LIFT HERE TO OPEN)
For Use on Dogs ONLY
Use ONLY on dogs
See inside flap for directions for use

Text for Foil of Blister package

Virbac
EFFTIXTM Plus Topical Solution For Dogs
Only for use on dogs (4 to 10.9 lbs, 11 to 22.9 lbs, 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/(0.017 oz ,0.034 fl oz,0.068 fl oz, 0.135 fl oz, 0.203 fl oz) [0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 6.0mL)
Contains fipronil (6.0%), permethrin (44.88%), and pyriproxyfen (1.8%)
KEEP OUT OF REACH OF CHtLDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2382-xxx
DO NOT USE ON CATS
CAT PROHIBITION ICON

Text for Applicator Tube

Virbac
EFFtTIX[™] Plus
Topical Solution For Dogs
Only for use on dogs
[4 to 10.9 lbs, 11 to 22.9 lbs 23-44.9 lbs, 45-88.9 lbs, 89-132 lbs)/
[0.017 fl oz, 0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz) [/ [0.5 mL (f.0 mL, 2.0 mL, 4.0 mL, 6.0mL)]
Contains fipronil (6.0%), permethrin (44.8%), and pyriproxyfen (1.8%)

KEEP OUT OF REACH OF CHILDREN CAUTION See full label for additional directions DO NOT USE ON CATS EPA Reg. No. 2382-XXX CAT PROHIBITION ICON

MARKETING CLAIMS

[Multiple infestations]

- For convenient, quick-acting, long-lasting, effective control of fleas, flea eggs, flea pupae, flea larvae, ticks, mosquitoes, and lice.
- [When [Applied topically on a monthty basis, EFFtTtXTM Plus Topical Solution for Dogs sepels and kills fleas, ticks and
 mosquitoes, kills flea eggs, flea larvae, (biting, chewing) lice, aids in the control of sarcoptic mites, and repels (and inhibits
 blood feeding by) biting flies and mosquitoes.
- [When) Applied topically on a monthly basis, EFFITIXTM Plus Topical Solution for Dogs repels and kills fleas, ticks and mosquitoes, kills flea eggs, flea tarvae, (biting, chewing) lice, aids in the control of mites that may cause sarcoptic mange, and repels Jand inhibits blood feeding by) biting flies and mosquitoes.
 For easy and convenient application, EFFITIXTM Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8]
- For easy and convenient application, EFFITIX: "Plus Topical Solution for Dogs is available in sizes for puppy/toy dogs [8 weeks old or older] and 4 to 10.9 lbs [0.17 fl oz][0.5 mL[, small dogs 11 to 22.9 lbs [0.034 fl oz][f.0 mL], medium dogs 23-44,9 lbs [0.068 fl oz] [2.0mL[, targe dogs 45-88,9 lbs]0,135 fl oz[[4.0 mL[, and extra targe dogs 89-132 lbs [0.203 fl oz] [6.0 mL].
- [6.0 mL].
 EFFITIX[™] Plus Topical Solution for Dogs contains the active ingredients fipronil, permethrin, and pyriproxyfen which control infestations caused by fleas, flea eggs, flea pupae, flea larvae, ficks and lice; repel Jageinst) biting files, and repet and kill mosquitoes.
- · Kills fleas, flea eggs, flea larvae, ticks, lice and mosquitoes, repels biting flies and mosquitoes
- Repels and kills fleas and ticks
- Repels fleas, ticks, billing flies and mosquitoes
- Kills and repels ticks
- · For the control and prevention of flea, flea egg, flea pupae, flea larvae, [and lice] infestations

EPA Reg. No. 2382-xxx page 4 of 7 - Pending Master tabet Submitted August 3, 2012

- Research has shown that flea, flea egg, flea pupae, flea larvae, tick (biting and chewing) lice infestations, can be controlled with monthly applications of EFFITIXTM Plus Topical Solution for Dogs. Biting flies and mosquitoes are Jalso] repelled by EFFITIXTM Plus Topical Solution for Dogs.
- Effective monthly application against fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes
- Kills fleas, flea eggs, flea larvae, ticks and mosquitoes for up to one month
- Monthly application is recommended for control and prevention of fleas, flea eggs, flea pupae, flea tarvae, ticks and mosquitoes
- Long lasting flea, flea egg, flea pupae, flea larvae, tick and mosquito control for your pet
- EFF(TIXTM Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, flea larvae, ticks, biting flies, mosquitoes, and lice on dogs 8 weeks of age and older
- Helps to relieve your dog's pain [discomfort] by controlling flea, flea egg, flea pupae, flea larvae, tick and lice infestations
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, anaplasmosis, ehrlichiosis, hepatozoonosis and heartworm disease.
- Kills fleas, flea eggs, flea tarvae, ticks, mosquitoes, tice, and aids in control of sarcoptic mites
- Kills fleas, flea eggs, flee larvae, ticks, mosquitoes, lice, and aids in controt of mites that may cause sarcoptic mange
- Kills and repets fleas, ticks, and mosquitoes.

[Fleas]

- Fleas: EFFITIX™ Plus Topical Solution for Dogs can kill adult fleas in 6 hours and adult fleas, flea eggs and flea larvae for up to three months. Apply monthly if your dog has fleas that may cause flea allergy dermatitis [FAD], or it reinfestation is
- Kills newly emerged adult fleas prior to egg laying
- Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with EFF(TIX™ Plus Topical Solution for Dogs
- Prevent all immature flea stages in the dog's environment from developing
- Sterilizes and kills (adult) fleas
- Prevents all flea stages [adult fleas, flea eggs, flea pupae and flea larvae]
- Prevents development of all flea stages [flea eggs, flea pupae and flea larvae) for up to [3 months] [90 days]
- Dual Action: fipronil and permethrin to kill adult fleas and pyriproxyfen to kill flea eggs and flea larvae
- With pyriproxyfen [IGR]* to break [the] flea tife cycle *insect growth regulator
- Kills fleas [within 6 hours] that may transmit bartonellosis, [tularemia] [and tapeworm]
- Kills fleas within 6 hours that may transmit the following diseases; partonellosis, (tularaemia) (and tapeworm infestations)
- Kills fleas [within 6 hours] that may transmit the following diseases: bartonellosis and tularemia
- Rapid kill of fleas is important in the prevention of the following diseases: bartonellosis and tularemia
- Acts to kill fleas that may transmit the following disease: bartonellosis and tularemia
- Kills fleas that may serve as an intermediate host for tapeworms [Dipylidium caninum]
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms
- Kills [adult] fleas [within 6 hours] that may cause Flea Allergy Dermatitis [FAD] [or] [flea-bite anemia[
- Fleas do not have to bite to die
- Controts highly [irritating] [annoying] [flea] bites
- EFFITIX™ Plus Topical Solution for Dogs rapidly kills fleas that may cause FAD (Flea Allergy Dermatitis)
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as Ftea Allergy Dermatitis [FAD]
- EFFITIXTM Plus Topical Solution for Dogs kills fleas and may reduce the incidence of Flea Allergy Dermatitis [FAD]
- Kills fleas which [that] may cause flea-bite anemia
- Effective monthly application against fleas, flea eggs, flea pupae, and flea larvae
- Effective monthly control of fleas, flea eggs, flea pupae, and flea tarvae
- Kills adult fleas for up to one month [4 weeks]
- Prevents flea eggs from hatching or developing into larvae or adult stages [for up to]90 days [3 months]]
- Kills adult fleas, flea eggs, and flea tarvae for up to three months [12 weeks] however if your dog is susceptible to Flea Allergy Dermatitis (FAD) it is recommended to use monthly
- Kills fleas, flea eggs, and flea larvae EFFITIX™ Plus Topical Solution for Dogs kills fleas, flea eggs, flea pupae, and flea tarvae on your dog
- Once a month topical flea control for dogs and pupples 8 weeks of age or older
- EFFITIX™ Plus Topical Solution for Dogs is indicated for the prevention and control of fleas, flea eggs, flea pupae, and flea larvae on dogs and puppies 8 weeks of age and older
- One application prevents further flea infestations for up to [12 weeks] [three months]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Monthly treatment [alt year] is recommended for control and prevention of fleas, flea eggs, flea pupae, and flea larvae
- Provides ongoing protection against fleas and the following diseases; bartonellosis,[tularemia]]and tapeworm infestations] they may transmit for one month
- Stops existing flea infestations by rapidly killing adult fleas, flea eggs, and flea larvae
- Kills fleas before they lay eggs
- Stops existing flea infestations by killing adult fleas, flea eggs, and flea larvae
- Prevents (Stops) re-infestations by killing adult fleas (before they tay eggs)
- Treatment with EFFITIXTM Plus Topical Solution for Dogs rapidly kills fleas which may cause flea allergic dermatitis JFADI or flea bite hypersensitivity
- Controls flea problems
- Provides flea protection
- Use flea [prevention] [protection[year-round

[Ticks]

- Ticks: EFFITIX^{IM} Plus Topical Solution for Dogs can kill ticks for [up to] at least [one] month. Apply monthly where tick controt is consistently needed.
- Kills and repels all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis[
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks (that may transmit Rocky Mountain Spotted Fever), Brown dog ticks (that may transmit ehrlichiosis), and Lone Star ticks (that may transmit hepatozoonosis[for up to one month [4 weeks)
- Kills ticks including Deer ticks [that may transmit Lyme disease and anaplasmosis], American dog ticks [that may transmit Rocky Mountain Spotted Fever), and Brown dog ticks [that may transmit ehrlichiosis) for up to one month [4 weeks].
- Kills Brown dog ticks [Rhipicephalus spp[, American dog ticks [Dermacentor variabilis), Deer ticks [txodes spp] and Lone Star ticks [Amblyomma americanum] for up to one month [4 weeks].
- Kills Lone Starticks (Amblyomma americanum) for 4 weeks (for up to one month[.
- Effective monthly application against ticks

[Mosquitoes and biting flies]

- Kills mosquitoes
- Kills mosquitoes for up to 28 days) four weeks [[a [one) month [
- Repels and inhibits blood feeding by biting flies and mosquitoes
- Biting flies and mosquitoes: When applied monthly, EFFITIXTM Plus Topical Solution for Dogs [prevents blood feeding by] [and] [repels] biting flies and mosquitoes for [up to) 4 weeks [a [one) month[
- Repels and kills mosquitoes for up to four [4] weeks
- Prevents blood feeding by mosquitoes
- Repels and prevents [inhibits[blood-feeding by biting flies
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [[Prevents blood-feeding by] [Kills and repels[[mosquitoes
- Repels biting flies
- Repels [[annoying[[bothersome[[nuisance]] biting flies
- Inhibits [[annoying[[bothersome [[nuisance]] biting flies
- [[Prevents][inhibits]] blood-feeding by biting flies
- Kills mosquitoes that may carry heartworm disease
- Repels and kills mosquitos (Cutex spp, Ochterofatus spp, Aedes spp) which may vector heartworm [Dirofilaria immitis] for one month

(Lice and Mites)

- Lice: EFFITIXTM Plus Topical Solution for Dogs can kill biting and chewing lice for a (ona) month. Apply monthly where lice control is consistently needed.
- Mites: [EFFITIX™ Plus Topical Solution for Dogs) aids in [the] control of mites that may cause sarcoptic mange.
- Mites: [EFFITIX Plus Topical Solution for Dogs] aids in [the] control of sarcoptic mites

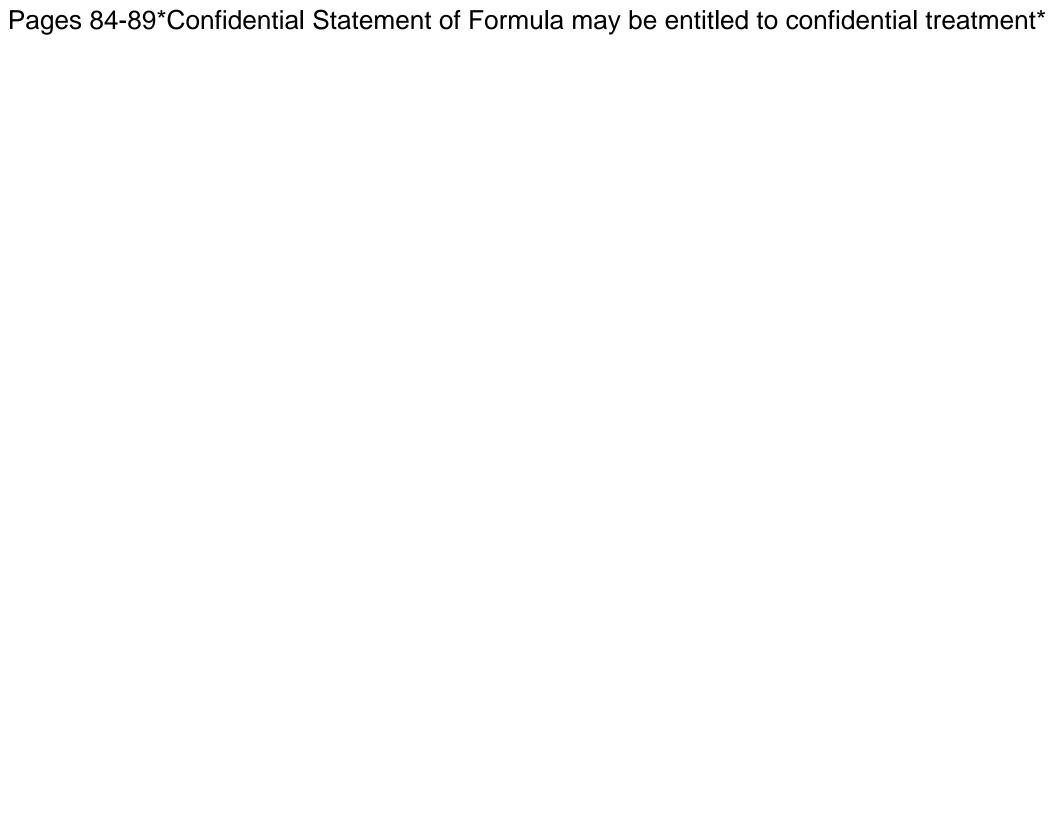
 EFFITIXTM Plus Topical Solution for Dogs aids in (the) control of mites that may cause sarcoptic mange.
- [When applied monthly], EFFITIXTM Plus Topical Solution for Dogs aids in [the[control of sarcoptic mange.
- Aids in [lhe] control of sarcoptic mange mite infestation
- Kills chewing and biting lice
-)Also) Kills lice and aids in control of mites that may cause sarcoptic mange
- [Also] Kills lice and aids in control of sarcoptic mites.
- Controls existing chewing/biting lice intestations
- Kills [(biting) (chewing[[lice
- For control and prevention of [[biting] [chewing]] lice [in/eslations]
- Slops existing [[biting) (chewing[] lice infestations
- Prevents and controls [[biting] [chewing][lice]in/estations]
- Provides effective control of [[biting] [chewing]] lice [infestations]
- Kills [(biting) [chewing]) lice and prevents further infestations
- For control and prevention of [in/estation[[with] [[biling[[chewing]] lice

[Others]

- 1 (3, 6, 36) applicator(s) (tube[s]) 0.5 mL (1.0 mL, 2.0 mL, 4.0 mL, 6.0 mL)
- 1 [3, 6, 36] applicator[s] [tube[s]] 0.017 fl oz [0.034 fl oz, 0.068 fl oz, 0.135 fl oz, 0.203 fl oz)
- 1 (3, 6, 36) applicator[s] [tube[s]) 0.017 fl oz [0.5 mL], [0.034 fl oz [1.0 mL], 0.068 fl oz [2.0 mL], 0.135 fl oz (4.0 mL], 0.203 fl oz [6,0 mL)
- 1 (3, 6, 36) applicator(s) [tube(s)) [each] containing 0.017 fl oz [0.5ml.] (0.034 fl oz [1.0 mL), 0.068 fl oz]2.0 mL), 0.135 fl oz [4.0 mL], 0.203 fl oz [6.0 mL]]
- 1 [3, 6, 36) applicator(s) (tube(s))
- 1 [3, 6, 36) monthly dose[s] [application[s]]
- 1 (3, 6, 36) applicator(s) (tube(s)) 1 (3, 6, 36) month(ly) dose(s) (application(s)
- DO NOT USE ON CATS
- This product is only for use on dogs and puppies 8 weeks of age or older and weighing 4 to 10.9 lbs, weighing 11 to 22.9 lbs, weighing 23 to 44.9 lbs, weighing 45 to 88.9 lbs, weighing 89 to 132 lbs)
- Easy and convenient application [applications[
- Remains effective for a [one) month [4 weeks] for fleas, flea eggs, flea larvae, flea pupae, ticks, mosquitoes and biting flies
- Stops exisling infestations and prevents establishment of new infestations for fleas and ticks
- Reinfestation of fleas, ticks and mosquitoes, [biting, chewing] lice and biting flies is pravented for a [one] month

- Convenient topical treatment for dogs
- Quick onset of activity
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Once monthly application
- Quick drying, non-greasy
- [Convenient] Ito use Easy Ito apply spot-on Itopical application
- Fragrance (odor) free
- No noticeable odors
- Single application lasts 4 weeks Jone month] [30 days]
- Easy to use applicator makes treatment simple [trouble free, smooth]
- Convenient, easy to apply topical solution
- Convenient, easy to apply and fragrance free topical solution
- Starts working by [on] contact
- [In] child-resistant packaging
- Convenient [to use], easy to apply [topical solution]

 EFFITIXTM Plus Topical Solution for Dogs remains effective after bathing, shampooing, water immersion, or sunlight exposure.
- Waterproof fremains effective after bathing and swimming[for up to four weeks [a month] Jone month]
- Remains effective after exposure to sunlight
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight
- Remains effective even after bathing [and swimming]
- Remains effective after exposure to rain and/or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Maintains residuat efficacy after bathing and swimming
- Remains effective after bathing [and swimming] [for a month] [for one month] [for up to four weeks][
- For dogs that enjoy the outdoors
- For indoor and outdoor dogs
- Convenient topical treatment for dogs who enjoy the outdoors
- Formulated for dogs that love the outdoors
- For dogs that enjoy the outdoors
- Sold by veterinarians
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of mite
- Illustration of louse
- Picture or illustration of a dog [or puppy]
- Picture or illustration of the Virbac togo
- Picture or illustration of the primary package [epplicator tubes]



Please read instructions on revers	e before completing form		For			0, Approval expires 5-31-98
	Unlf	ed States		X Registratio		OPP Identifier Number
♦EPA	Environmental Protection Agency			Amendmer Other	٦t	
	Washington, DC 20460					
			sticide – Sectio	n I		
Company/Product Number Virbac AH, Inc./ 2382- xxx			EPA Product Ma Richard Gebken	inager	3. Propos	ed Classification
4. Company/Product (Name) EFFITIX™ PLUS Topical Solu	tion for Dogs		PM# 10		X Non	e Restricted
5. Name and Address of Appl Virbac AH, Inc P.O. Box 162059 Fort Worth, TX 76161	Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc P.O. Box 162059				e with FIFF Il in compo	RA Section 3(c)(3) silion and labeling
Check if this is a new ad	dress		EPA Reg No. Product Name			
			<u> </u>			_
		Secti	on - II			
Amendment – Explain be	elow		Final printed	labels in respons	e to	
Resubmission in respon	se to Agency letter dated		Agency lette	er dated oplication		
Notification – Explain be	low		X Other – Exp	lain below		
Explanation: Use additional	page(s) if necessary. (Fo	r Section I and Sec	ction II.)			
Application for EFFITIX				0. Please refer	to attacl	hed letter.
		•				
		Sect	ion III			
Material This Product Will I		l IAI	star Calcible Dealracia		O T	
Child-Resistant Packaging x Yes	Unit Packaging X Yes	\ \[\partial \qquad \qq	ater Soluble Packagin Yes	9	Me Me	
No	No No	×	No		X Pla Gla	stic, PETE ss
*Certification must	If "Yes"		Yes"	No. per	Par	per
be submitted	Unil Packaging wgt. 0.5	container	ckage wgt	container		ner (Specify)
3. Location of Net Contents In		4. Size(s) Relai	l Container			el directions
Label	x Container	1, 3, 6 ml tubes			n Label n Label ad	companying product
6. Manner in Which Label is A	Affixed to Product	Lithograph		Olher		, , , , , , , , , , , , , , , , , , , ,
		X Paper glue Stenciled	ed			
			ion IV			
Contact Person (Complete	items directly below for it		vidual to be contacled			
Name Craig Parks, MS, DVM		Title Vice Presid	lent of Research and	Telepho 682-64		nclude Area Code)
Orang a anka, mo, byter		Developme Virbac AH,	ent,	332 31		
	Ce	rtification		<u> </u>	6.	Date Application
t certify that the statements I h	ave made on this form and gly false or misleading sta	l all attachments th tement may be pun	ereto are true, accurat ishable by fine or impi	e and complete. risonment or		Received
both under applicable law 2. Signature		3, Title				(Stamped)
1.01			sident of Research and Development,			- , ,
(rosy Kark		The de lain,				
4. Typed Name 5. Date Crain Parks MS DVM August 3. 2012						

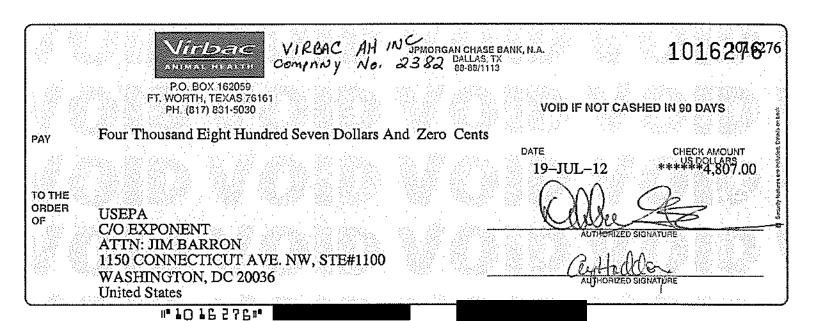
EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

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Please read Instructions on reverse	before completing form		F				60, Approval expires 5-31-98
	Unite	ed States		X Re	gistratio	n	OPP Identifier Number
\$EPA	Environmental	Protection Ag	jency		endmei	nt	
	Washington, DC 20460				ner		
			esticide - Secti	on I	·		<u> </u>
t. Company/Product Number			2. EPA Product I	Vianager	T i	3. Propos	sed Classification
Virbac AH, Inc./ 2382- xxx 4. Company/Product (Name)			Richard Gebken PM#			X No	ne Restricted
EFFITIX™ PLUS Topical Solution			10				
5. Name and Address of Applic	cant (Include ZIP Code)						RA Section 3(c)(3)
Virbac AH, Inc P.O. Box t62059			(b)(i), my product	is similar o	or identica	at in comp	osition and labeling
Fort Worth, TX 76161			EPA Reg No.				
Check if this is a new add	imaa		Product Nama				
Check it this is a new add			Product Nama				
		Section	ion - II				
Amendment – Explain bet	low	Ocot		ed labels in	respons	e to	
			[]	tter dated_	•		
Resubmission in response	e to Agency letter dated		"Me Too"	Application			
· ·				•			
Notification - Explain belo)W		X Other - E	xplain belov	w		
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Explanation: Use additional page	age(s) if necessary. (For	Section I and Se	ction II.)				
	N 110					4	L - 11.0
Application for EFF(TIX P	LUS new product n	egistrati on . PR	IIA Category R3	10. Pleas	se reter	to attac	ned letter.
		Sect	ion III				
t. Material This Product Will be	Packaged in:						
Child-Resistant Packaging	Unit Packaging	W.	ater Soluble Packag	ing			of Container
x Yes	X Yes		Yes		ļ		etal estic, PETE
No	No	[7	No				ass
*Certification must	If "Yes"	No, per If "	Yes"	No. pe	er		per
be submitted	Unit Packaging wgt.		ickage wgt	contai	iner	Ctl Otl	her (Specify)
2 Leasting of Not Contacts Lef	0.5	t,3,6,36	i Oastalaaa			tian af lo	pel directions
3. Location of Net Contents Inf	Container	4. Size(s) Reta t, 3, 6 ml tubes				n Label	oei directions
							ccompanying product
6. Manner in Which Label is Af	fixed to Product	Lithograph		Ct Ot	her		
		X Paper glue Stenciled	ed				
			ion IV				
t. Contact Person (Complete i	tems directly below for id			ed, if neces	sary, to p	process th	is application.)
Name		Title	<u></u>		Telepho	one No. (I	nclude Area Code)
Craig Parks, MS, DVM		Vice Presid	dent of Research an	d	682-64	7-3576	
		Virbac AH,					
		tification				6.	Date Application
I certify that the statements I have							Received
I acknowledge that any knowing both under applicable law	il impe or musicating stat	entent may be bull	usuante by title of Im	huzoumeni	. 01		
2. Signature	<u></u>	3. Title					(Stamped)
1.11			ient ot Research an	d Developr	ment,		
(easy take		Virbac AH,	IIIG.				
4. Typed Name		5. Date					
Craig Parks, MS, DVM		August 3, 2	2012				
EPA Form 8570-1 (Rev. 8-94) P.	revious editions are obsot	ete.	Wh	itc – EPA F	tie Copy (Original)	Yellow - Applicant Copy

Commercial/financial information may be entitled to confidential treatment

		₹		'		
Invoice	Date	Invoice	Description	Gross Amount	Discount	Invoice Amount
071312US	13-JUL-12	REGISTE	RATION FEE EFF	4,807.00	0.00	4,807. 00
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		TOTALS		4,807.00	0.00	4,807.00





August 2, 2012

Richard Gebken, PM 10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject:

EFFITIX™ PLUS Topical Solution for Dogs (EPA File Symbol 2382-TBA);

New Product Application.

Dear Mr. Gebken,

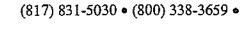
Virbac Animal Health (Virbac AH, Inc. P. O. Box 162059, Ft. Worth, TX 76137, (Company Number 2382) is hereby submitting an application to register the spot-on pesticide product EFFITIXTM PLUS Topical Solution for Dogs.

This product contains the active ingredients fipronil at 6.0% w/w, permethrin at 44.8%, and pyriproxyfen at 1.8 % w/w and is intended to control fleas, ticks, mosquitoes, and other pests in dogs only.

As indicated on Form 8570-34, Virbac is using the selective method to address applicable data requirements for this application pursuant to 40 CFR 152.90. Pursuant to 40 CFR 152.93, Virbac is issuing Offer to Pay letters to the submitters of data not owned by Virbac and cited in this application that were originally submitted to EPA within the past 15 years.

Below is a list of the components included with this application:

- Cover Letter;
- 2. Transmittal Document;
- 3. Application for Pesticide Form 8570-1 for EFFITIX™ PLUS Topical Solution For Dogs;
- 4. Confidential Statement of Formula for EFFITIXTM PLUS Topical Solution for Dogo; •
- 5. Data Matrix Form 8570-4 for EFFITIXTM PLUS Topical Solution for Dogs;
- Certification of Data Citation Form 8570-34 For EFFITIX[™] PLUS Topical Solution For Dogs;
- 7. Proposed Use Directions for EFFITIXTM Topical Solution for Dogs 5 copies;
- 8. 3 copies of bound PR 86-5 compliant study reports supporting registration;
- 9. Waiver Request for Acute Inhalation Study (attached to Cover Letter);
- 10. Letter of Self-certification of Child-Resistant Packaging;
- 11. Copy of PRIA Check for category R-310 (\$4807).



Waiver Request

Registrant: Virbac Animal Health, Inc. Acute Inhalation Study (OPPTS 830.1300). Brandname: Effitix[™] PLUS Topical Solution for Dogs.

The Effitix PLUS Topical Solution for Dogs product is composed of 6.0% w/w of the active ingredient fipronil, 44.8% w/w of the active ingredient permethrin and 1.8% w/w of the active ingredient pyriproxifen. This product is packaged in single use non-refillable applicators that are intended for one time only spot-on applications to dogs.

The potential human inhalation exposure to this product is expected to be neglible. Only very small amounts of product are applied per application, depending the weight of the animal. Based on packaging considerations described in the proposed product labeling, the maximum volume of Effitix PLUS Topical Solution that can be administered at one time to a pet using the largest available applicator size is approximately 6.0 ml. This application volume represents the worst case because it is the dose that is recommended only for use on dogs weighing more than 89 pounds. Therefore, according to the proposed label, a great deal of anticipated product use will occur at much lower volumes on smaller dogs.

Furthermore, the measured vapor pressure of all three active ingredients fipronil permethrin, and pyriproxifen are extremely low (2.8 x 10⁻⁹ mm Hg @ 25°C, 2.18 x 10⁻⁸ mm Hg @ 25°C, and 1.0 x 10⁻⁷ mm Hg @ 20°C, respectively) indicating that all three active ingredients are essentially non-volatile and are therefore not expected to vaporize from the skin of the treated animal following application. The active ingredients will therefore not be available for inhalation after application according to label directions. Finally, the method of applying the liquid product directly to the pet creates no particulates, aerosols, or other respirable matter. Therefore, based on the criteria provided by the Agency in 40 CFR 158.500, footnote 4 under the Toxicology Data Requirements, a waiver of the acute inhalation study for these products is appropriate.



August 3, 2012

Richard Gebken, PM 10 Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Document Processing Desk Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

Subject:

Child Resistant Packaging Certification EFFITIXTM PLUS Topical Solution for Dogs;

EPA Reg. No. 2382-TBA

Dear Mr. Gebken:

I certify that the packaging used for the following product meets the standards of 40 CFR 157.32, including the revised standards in 16 CFR 1700.15(b), when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995).

EFFITIXTM PLUS Topical Solution for Dogs (EPA Reg. No. 2382-TBA).

Should you have any questions about this letter, please do not hesitate to contact me via telephone at 682-647-3576 or via e-mail at craig.parks@virbacus.com.

Sincerely,

Craig Parks, MS, DVM

Vice President, Research & Development

Virbac Animal Health, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M STREET, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.						
Certification with	Respect to Citatio	on of Data				
Applicant's/Registrant's Name, Address, and Telephone Number Virbac AH, Inc./ PO Box 162059 Fort Worth TX 76137/ telepho	EPA Registration Number/File Symbol 2382-NEW					
Active Ingredient(s) and/or representative test compound(s) Fipronil, permethrin, pyriproxyfen		Date August 3, 2012				
General Use Pattern(s) (list all those claimed for this product using 40 C indoor residential	CFR Part f58)	Product Name EFFITIX ™ PLUS Topical Solution for Dogs				
NOTE: If your product is a f00% repackaging of another purchased EF to submit this form. You must submit the Formulators Exemption State						
I am responding to a Data-Call-tn Notice, and have included w should be used for this purpose).	ith this form a list of (companies sent offers of compensation (the Data Matrix form				
SECTION I: METHOD OF DA	TA SUPPORT (Ched	k one method only)				
I am using the cite-all method of support, and have included w this form a list of companies sent offers of compensation (the l Matrix form should be used for this purpose)	Data A u	am using the selective method of support (or cite-all option nder the selective method), and have included with this form completed list of data requirements (the Data Matrix form oust be used).				
SECTION (1: G	ENERAL OFFER TO	PAY				
[Required if using the cite-all method, or when using the cite-all option u	ınder the selective m	ethod to satisfy one or more data requirements]				
I hereby offer and agree to pay compensation, to other person	s, with regard to the	approval of this application, to the extent required by FIFRA				
SECTION	tii: CERTIFICATIO	ł .				
I certify that this application for registration, this form for reregist the application for registration, the form for reregistration, or the Data-C selective method is indicated in Section f, this application is supported product or an identical or substantially similar product, or one or more of be submitted under the data requirements in effect on the date of appropriate or similar composition and uses.	all-tn response, tn ac by all data in the Age of the ingredients in th	Idition, if the cite-all option or cite-all option under the ncy's files that (1) concern the properties or effects of this is product; and (2) is a type of data that would be required to				
I certify that for each exclusive use study cited in support of this obtained the written permission of the original data submitted to cite that		stration, that I am the original data submitter or that I have				
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) t have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(8) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.						
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.						
I certify that the statements t have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.						
Signature	Date	Typed or Printed Name and Title				
Craig Kah	August 3, 2012	Craig Parks Vice President, R&D Virbac Animal Health, Inc.				

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Product ingredient source information may be entitled to confidential treatment

		ved. OMB No. 2070-0060. Approval expires 5-31-98					
die Malle man, ort	United States Environmental Protection Agency						
\$EPA	Washington, DC 20460						
For	mulator¹s Exemption Statement						
	(40 CFR 152.85)						
Applicant's Name and Address Virbae Animal Health	EPA File Symbol/ 2382-NEW	Registration Number					
P. O. Box 162059	Product Name						
Ft. Worth, TX 76137		Topical Solution for Dogs					
	Date of Confident July 12, 2012	ial Statement of Formula (EPA Form 8570-4)					
As an authorized representative of the applicant		I certify that:					
(1) This product contains the following active in	ngredient(s):permethrin						
	another product which contains that active ingr producer, and is labeled for at least each use for	edient which is registered under FIFRA					
(3) Indicate by checking (12) of (5) ocies, while	n paragraph apphes.						
	of Formula (EPA FORM 8570-4) for the above indicates, by company name, registration numb aph (1)						
	OR						
	nula (CSF) (EPA Form 8750-4) referenced abov the information required on the current CSF	e and on file with the EPA is complete,					
(4) The following active ingredients in this pro-	duct qualify for the formulator's exemption	***************************************					
	Source						
Active Ingredient	Product Name	Registration Number					
Permethrin							
t Clinethin							
Pyriproxyfen							
Tytiploxyton							
	,						
Signature Cray Rah	Name and Title Vice President, Research & Development	Date August 3, 2012					
Signature (Lacy Kuru .							

EPA Form 8570-27 (Rev. 8-95)

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	· · · · · · · · · · · · · · · · · · ·	ved, OMB No. 2070-0060. Approval expires 5-31-98
	United States	į
&EPA	Environmental Protection Agency Washington, DC 20460	***************************************
	mulator's Exemption Statement	- -
ron	(40 CFR 152,85)	•
Applicant's Name and Address	(11 = 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	Registration Number
Virbac Animal Health	2382-NEW	Registration (vanioe)
P. O. Box 162059	Product Name	
Ft. Worth, TX 76137		Topical Solution for Dogs
	Date of Confident July 12, 2012	ial Statement of Formula (EPA Form 8570-4)
As an authorized representative of the applicant		, I certify that:
(1) This product contains the following active in	ngredient(s):permethrin	
	agraph (4) is present solely as the result of the another product which contains that active ing producer, and is labeled for at least each use fo	redient which is registered under F1FRA
(3) Indicate by checking (A) or (B) below whic	h paragraph applies:	
	of Formula (EPA FORM 8570-4) for the abovindicates, by company name, registration number (1)	
	OR	
	nula (CSF) (EPA Form 8750-4) referenced aborne information required on the current CSF	ve and on file with the EPA is complete,
(4) The following active ingredients in this production	duct qualify for the formulator's exemption	
	Source	***************************************
	Source	
Active Ingredient	Product Name	Registration Number
Permethrin		
remental		-
		<u> </u>
Pyriproxyfcn		·
		
•		1
	Name and Title	Doto
1.61	Name and Title Vice President, Research & Development	Date August 3, 2012
Signature Craix lake		

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy Yellow - Applicant copy *Product ingredient source information may be entitled to confidential treatment*

Form Approved. OMB No. 2070-0060. Approval expires 5-31-98 United States **Environmental Protection Agency** Washington, DC 20460 Formulator's Exemption Statement (40 CFR 152.85) Applicant's Name and Address EPA File Symbol/Registration Number Virbac Animal Health 2382-NEW P. O. Box 162059 Product Name Ft. Worth, TX 76137 EFFITIXTM PLUS Topical Solution for Dogs Date of Confidential Statement of Formula (EPA Form 8570-4) July 12, 2012 As an authorized representative of the applicant for registration of the product identified above, I certify that: (1) This product contains the following active ingredient(s):permethrin (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled. (3) Indicate by checking (A) or (B) below which paragraph applies: (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (I) (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF (4) The following active ingredients in this product qualify for the formulator's exemption Source Active Ingredient Product Name Registration Number Permethrin Pyriproxyfen Name and Title Date Vice President, Research & Development August 3, 2012

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	DA	TA MATRIX			
Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TBA	Page 6 of tt	
Applicant's/Registrant's Name & A	ddress		Product:		
Virbae AH, the					
PO Box 162059			EFFITIX 1M PLUS TOPICAL SOLUTION	FOR DOGS	
Fort Worth TX 76161	· · · · · · · · · · · · · · · · · · ·				
Ingredient: Fipronil, Permethrin Pyr Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Guideline Study Natic	MIKITA Manuper	Submitter	Status	NOIC
Efficacy and safety data -Fipronil					
810.3300	Product Performance Efficacy-Mange	¥5620504	Merial	PAY	
810.3300	Product Performance Efficacy-Mange	45620505	Merial	PAY	
810.3300	Product Performance Efficacy-Mange	45620506	Merial	PAY	
810.3300	Product Performance Efficacy-Miles	°,43444901	Merial	OLD	
810.3300	Product Performance Efficacy-Mites	`43577701	Merial	OLD	
810.3300	Product Performance - Efficacy-Mites	43951701	Merial	OLD	1
810.3300	Product Performance - Efficacy-Mites	45612701	Merial	PAY	
810,3300	Product Performance - Efficacy-Mites	45620503	Merial	PAY	
810.3300	Product Performance - Efficacy-Miles	45866901	Merial	PAY	· · · · · ·
810.3300	Product Performance Efficacy-Lice	45620501	Merial	PAY	
810.3300	Product Performance Efficacy-Lice	45628101	Merial	PAY	
810.3300	Product Performance Efficacy-Lice	45628102	Merial	PAY	
810.3300	Product Performance Efficacy-Lice	45628103	Merial	PAY	
810.3300	Product Performance - Efficacy-Lice	45628201	Merial	PAY	
810.3300	Product Performance Efficacy-Mosquito	45866902	Merial	PAY	
810.3300	Product Performance - Efficacy-Mosquito	46019202	Merial	PAY	
810.3300	Product Performance Efficacy-Mosquito	46019201	Merial	PAY	
Signature			Name and Title		Date
Craig Lahr			Craig Parks		July 31,
care our	II. 4 (14 (1) 4)		Vice President, Research & Development		2012

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Date July 31, 2012			EPA Reg. No./File Symbol 2382-TBA	EPA Rcg. No./File Symbol 2382-TBA		
Applicant's/Registrant's Name & A	ddress		Product:			
Virbac AH, Inc						
1 ^c O Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTIO	N FOR DOGS		
Fort Worth TX 76161				***************************************		
Ingredient Fipronil, Permethrin.Pyri Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Noic	
Efficacy and safety data	Guideline Study Name	WIND MILLIOUS	Supinitiet	Sialus	Noic	
-Fipronil						
810.3300	Product Performance - Efficacy-flea	~44942106	Merial	PAY		
810.3300	Product Performance - Efficacy-flea	-45618501	Merial	PAY		
810.3300	Product Performance - Efficacy-flea	45620502	Merial	PAY		
810.3300	Product Performance - Efficacy-flea	45620503	Merial	PAY		
810.3300	Product Performance - Efficacy-flea	45628104	Merial .	PAY		
810.3300	Product Performance - Efficacy-flea	45628105	Merial	PAY		
810.3300	Product Performance - Efficacy-flea	45866901	Merial	PAY		
810.3300	Product Performance - Efficacy-lick	43577712	Merial	OLD		
810.3300	Product Performance - Efficacy-lick	. 43121114	Merial	OLD		
810.3300	Product Performance - Efficacy-tick	43121115	Merial	OLD		
810,3300	Product Performance - Efficacy-tick	43121117	Merial	OLD		
810.3300	Product Performance - Efficacy-tick	43121122	Merial	OLD		
810.3300	Product Performance- Efficacy Bathing	43121118	Mcrial	OLD		
Signature			Name and Title	•	Date	
Caning Rach			Craig Parks Vice President, Research & Development		July 31, 2012	

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	D	ATA MATRIX			
Date; July 31, 2012	***************************************		El ^t A Reg. No./File Symbol 2382-TBA		Page 4 of 11
Applicant's/Registrant's Name & A	ddress		froduct:		1
Virbac AH, Inc					
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTI	ON FOR DOGS]
Fort Worth TX 76161					1
Ingredient: Fipronil, Permethrin, Pyr Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and safely data	Guidenite Study Name	MICE Number	Sabilitati	Status	Note
-Fipronil					
810.3300	Product Performance - Efficacy-flea	43121114	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121115	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121116	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121119	Merial	- OLD	
810.3300	Product Performance - Efficacy-flea	43121120	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121121	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43121122	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43444901	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43577701	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43577712	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	43577713	Merial	OLD	
810.3300	Product Performance – Efficacy-flea	43951701	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	44088901	Merial	OLD	
810.3300	Product Performance - Efficacy-flea	44942011	Merial	PAY	
Signature			Name and Title	•	Date
Cray hale			Craig Parks Vice President, Research & Developmen	nt	July 31, 2012

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	DAT	TA MATRIX			
Date: July 31, 2012			EPA Reg. No./File Symbol 2382- TBA		Page 3 of tt
Applicant's/Registrant's Name & A	ddress		Product:		
Virbae AH, Inc					
PO Box 162059			EFFITIX ™ TOPICAL SOLUTION FOR DOC	3S	
Fort Worth TX 76161	*				
Ingredient: Fipronil, Permethrin.Pyr Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Data	Ouldering Study Haine	WIKID Mullioci	Guotifici	Status	Note
870.7200	Companion Animal safety 14 d pup study-1	48487302	Virbae AH, Inc	OWN	
870.7200	Companion Animal safety-Beagle Dog	* 48467117	Virbac AH, Inc.	OWN	
		·48467118	Virbae AH, Inc.	OWN	
870.7200	Companion Animal safety-14 d pup study-2				
870.7200	Companion Animal safety Summary	-48467119	Virbae AH, Inc	OWN	ļ
870.7200	Companion Animal safety - Method Valid.	48467120	Virbae AH, Inc	OWN	
810.3300	Product Performance -Flea onset of Action	48510701	Virbae AH, Inc	OWN	
810.3300	Product Perfonnance - Rhipiciphalus action	48467122	Virbae AH, 1nc.	OWN	
810.3300	Product Performance -D. variablis action	48467123	Virbae AH, Inc	OWN	
810.3300	Product Performance - Shampoo study	48467124	Virbac AH, Inc	OWN	
810.3300	Product Performance - Amblyoma efficacy	48467125	Virbae AH, Inc	OWN	
810.3300	Product Performance Ixodes efficacy	48467126	Virbae AH, Inc.	OWN	
810.3300	Product Performance - Mosquito efficacy	48467127	Virbac AH, Inc	OWN	
810.3300	Product Performance - Tick repellency	48467128	Virbae AH, Inc	OWN	
810.3300	Product Performance - Efficacy Summary	48467129	Virbac AH, Inc.	OWN	
Efficacy and Safely Data-					
Fipronil				1	
870.7200	Companion Animal safety	43444905	Merial	OLD	
870.7200	Companion Animal safety	43577711	Merial	OLD	
870.7200	Companion Animal safety	43863802	Merial	OLD	
870.7200	Companion Animal safety	43121110	Merial	OLD	
870.7200	Companion Animal safety	43121111	Merial	OLD	
870.7200	Companion Animal safety	45612702	Merial	PAY	
Signature			Name and Title		Date
Cany hacher		•	Craig Parks Vice President, Research & Development		July 31, 2012
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	DA	TA MATRIX			
Date: July 31, 2012		EPA Reg. No./File Symbol 2382- TBA	Page 2 of t		
Applicant's/Registrant's Name & A	ddress	Product:			
Virbae AH, Inc					
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTION F	OR DOGS	
Fort Worth TX 76161					
Ingredient: Fipronil, Permethrin,Py	·-^				1
Goldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry 830 Series	Group B Test Guidelines	•			
830.7100	Viscosity	New Submission	Virbac All, Inc.	OWN	
830.6319	Miscibility		Virbae AH, Inc	NR	
830,6320	Corrosion characteristics	To Be Conducted	Virbac AH, Inc.	OWN	
830.6321	Dielectrie breakdown voltage		Virbac AH, Inc	NR	
830.7000	pI-l	New Submission	Virbac AH, Inc.	OWN	
830.7300	Density, bulk density, or specific gravity	New Submission	Virbac AH, Inc	OWN	
830.7320	Particle Size distribution		Virbac All, Inc.	NR	
40 CFR 158.340 Toxicology D	ata Requirements			***	
870.1100	Acute oral toxicity	New Subrission	Virbac Al·l, Inc.	OWN	
870.1200	Acute dermal toxicity	New Submission	Virbac AH, Inc	OWN	
870.1300	Acute inhalation toxicity	Waiver requested	Virbac AH, Inc.	OWN	waiver
870.2400	Primary eye irritation	New Submission	Virbac AH, Inc	OWN	
870.2500	Primary dermal irritation	New Submission	Virbac AH, Inc.	OWN	
870.2600	Dermal sensitization	New Submission	Virbac AH, Inc	OWN	
Signature	•		Name and Title	<u></u>	Date
			Craig Parks		July 31,
Cray take			Vice President, Research & Development		2012
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	D _A	ATA MATRIX			
Date: July 31, 2012			EPA Reg. No./File Symbol 2382- TBA	Page t of t	
Applicant's/Registrant's Name & A	ddress		Product;	Product;	
Virbac AH, tnc.					
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTION FO	1	
Fort Worth TX 7616t					
Ingredient: Fipronil, Permethrin.Py		Liminar	L 0-1 20	1 0	1 32-1-
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry 830 Series		1		OUD!	<u> </u>
830.1550	Product Identity and Composition	New Submission	Virbae AH, Inc.	OWN	
830.1600	Description of Malerials Used	New Submission	Virbae AH, Inc	OWN	<u> </u>
830.1620	Description of Production Process	New Subutission	Virbae AH, Inc.	OWN	
830.1650	Description of Formulation Process	New Submission	Virbac AH, Inc	OWN	
830.1670	Description of Formation of Impurities	New Submission	Virbae AH, Inc.	OWN	
830.1750	Certified Limits	New Submission	Virbae AH, Inc	OWN	
830.1700, 830.1800	Analytical Method	New Submission	Virbae AH, Inc.	OWN	
Product Chemistry 830 Series	Group B Test Guidelines	-			
830.6302	Color	New Submission	Virbae AH, Inc	OWN	
830.6303	Physical State	New Submission	Virbae AH, Iuc.	OWN	
830,6304	Odor	New Submission	Virbae AH, Inc	OWN	
830.6313	Metal Stability		Virbae AH, Inc.	NR	
830.6314	Oxidation/reduction	New Submission	Virbae AH, Inc	OWN	
830.6315	Flammability	New Submission	Virbac AH, Inc.	OWN	
830.6316	Explodability		Virbae AH, Inc	NR	
830.6317	Storage stability	To Be Conducted	Virbae AH, Inc.	OWN	
Signature Leavy Kah			Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012

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	DA	TA MATRIX			
Date July 31, 2012			EPA Reg. No./File Symbol 2382-fBA	Page 7 of tt	
Applicant's/Registrant's Name & Address			Product:		1
Virbae AH, Inc			MAINTENA NA PARAMANTA IL AGUNDONIA	BAR BAAA	
PO Box 162059 Fort Worth TX 76161			EFFITIX ™ PLUS TOPICAL SOLUTION	FOR DOGS	
Ingredient: Fipronil, Permethrin, Pyri	ifan				1
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Efficacy and Safety Dala-	- Guideline Bludy Plante	MIGD Mullion	Buolineel	Buttab	11010
Permethrin					
870.7200	Companion Animal safety	41056906	Coopers Animal Health, Inc	OLD	
870.7200	Compartion Animal safety	41953201	Coopers Animal Health, Inc.	OLD	
870.7200	Companion Animal safely	43137201	Hartz Mountain Corporation	OLD	
870.7200	Contpanion Animal safety	43447101	Hartz Mountain Corporation	OLD	
870.7200	Companion Animal safety	43396408	ECTO Development Corporation	OLD	
870.7200	Companion Animal safety	43612601	ECTO Development Corporation	OLD	<u> </u>
810.3300	Product Performance - Efficacy	41038802	Cooper's Animal Health	OLD	Ì
810.3300	Product Performance - Efficacy	41038803	Cooper's Animal Health	OLD	
810.3300	Product Performance - Efficacy	43137202	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43137203	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	46006002	Wellmark	PUB	
810.3300	Product Performance - Efficacy	41683903	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43111607	Hartz Mountain Corporation	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
810.3300	Product Performance - Efficacy-Biting Fly	46978901	Bayer Healtheare LLC	PAY	11-13-06
Signature			Name and Titte Craig Parks Vice President, Research & Development		Date July 31, 2012
1955 the contract of the contr					

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		DATA MATRIX			
Date: July 31, 2012			EPA Rcg. No./File Symbol 2382-TBA	Page 8 of tl	
Applicant's/Registrant's Name & Address			Product:		
Virbae AH, Inc					
PO Box 162059			EFFITIX ™ TOPICAL SOLUTION FOR D	OGS	
Fort Worth TX 76161	10				
Ingredient; Fipronil, Permethrin. Pyrip		Lympy	Laterine	Lau	1 37
Guideline Reference Number			Submitter	Status	Note
Efficacy and Safety Data-					
Permethrin					
810.3300	Product Performance - Efficacy	42256901	Cooper's Animal Health, Inc.	OLD	
810.3300	Product Performance - Efficacy	43396409	Ecto Development Corporation	OLD	
810,3300	Product Performance - Efficacy	43396410	Ecto Development Corporation	OLD	
Efficacy and Safety Data-					
Pyriproxifen					
870.7200	Companion Animal safety	43396408	Ecto Development Corporation	OLD	
870.7200	Companion Animal Safety	43612601	Ecto Development Corporation	OLD	
870.7200	Companion Animal Safety	44900902	Virbae AH, Inc.	OWN	
870.7200	Companion Animal Safety	44900903	Virbac Al-l, Inc.	OWN	
870,7200	Companion Animal Safety	42178309	Sumitomo Chemical Company, Ltd.	OLD	
810,3300	Product Performance - Efficacy	44900904	Virbac AH, Inc.	OWN	
810,3300	Product Performance - Efficacy	45020601	Virbac AH, Inc.	OWN	
Signature			Name and Title	•	Date
			Craig Parks		July 31,
Craig Rah			Vice President, Research & Development		2012

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Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TBA	EPA Reg. No./File Symbol 2382-TBA		
	rant's Name & Address		Product;			
Virbae AH, Inc						
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTIO	N FOR DOGS		
Fort Worth TX 76	il, Permethrin.Pyriproxifen					
Guideline Reference		MRID Number	Submitter	Status	Note	
Child Resistant						
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 1 applicator tube test as a Poison Prevention Package for Virbae SA	48467130	Virbae AH, Inc.	OWN		
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 3 applicator tubes test as a Poison Prevention Package for Virbae SA	48467131	Virbac All, Inc	OWN		
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0 ml water, 6 applicator tubes test as a Poison Prevention Package for Virbae SA	48467132	Virbae Al-l, Inc.	OWN		
40 CFR 157	Evaluation of the 1ml Applicator Tube with 1.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbae	48467133	Virbae Al·l, Inc	OWN		
40 CFR 157	Evaluation of the 3rd Applicator Tube with 2.0rd water, 1 applicator tube test as a Poison Prevention Package for Virbae SA	48467134	Virbae AH, Inc.	OWN		
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbae SA	48467135	Virbac Al-l, lue	OWN		
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbae SA	48467136	Virbae All, Inc.	OWN		
Signature	en han		Name and Title Craig Parks Vice President, Research & Development		Date July 31, 2012	

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	DAT	A MATRIX	·		
Date: July 12, 2012		EPA Reg. No./File Symbol 2382-TBA	Page t0 of tt		
	nt's Name & Address		Product:		
Virbac All, Inc					
PO Box 162059			EFFITIX ™ PLUS TOPICAL SOLUTION	FOR DOGS	
Fort Worth TX 7616					<u> </u>
Guideline	Permethrin Pyriproxifen	MRID Number	Submitter		Note
Reference Number	Guideline Study Name	MICH Number	Submitter	Status	Note
40 CFR 157	Evaluation of the 3ml Applicator Tube with 2.0ml water, 36 applicator tubes test as a Poison Prevention Package for Virbae SA	48467137	Virbac Al-l, luc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 1 applicator tube test as a Poison Prevention Package for Virbae SA	48467138	Virbae Al-l, lue	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467139	Virbae Al-l, Inc.	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 6 applicator tubes test as a Poison Prevention Package for Virbae SA	48467140	Virbac Al-l, Inc	OWN	
40 CFR 157	Evaluation of the 6ml Applicator Tube with 4.0ml water, 36 applicator tubes test as a Poison Prevention Fackage for Virbae SA	48467141	Virbac All, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator fube with 6.0ml water, I applicator tube test as a Poison Prevention Package for Virbac SA	48467142	Virbac AH, Inc	OWN	Vol 43
Signature	de.		Name and Titte Craig Parks Vice President, Research & Development		Date July 3 t, 2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

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	DATA	MATRIX			
Date: July 31, 2012			EPA Reg. No./File Symbol 2382-TI	BΛ	Page 11 of 11
Applicant's/Registran	t's Name & Address		Product:	-	
Virbac AH, Inc					
PO Box 162059			EFFI'f1X ™ PLUS TOPICAL SOLU	JITON FOR DOGS	
Fort Worth TX 76161					L
	ermethrin, Pyriproxifen				
Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
Nimber					
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water, 3 applicator tubes test as a Poison Prevention Package for Virbac SA	48467143	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water,6 applicator tubes test as a Poison Prevention Package Virbae SA	48467144	Virbac AH, Inc	OWN	
40 CFR 157	Evaluation of the 6 ml Applicator Tube with 6.0ml water,36 applicator tubes test as a Poison Prevention Package for Virbae SA	48467145	Virbac AH, Inc.	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Child-Resistant Effectiveness	48095215	Virbae Al-l, Inc.	OWN	1
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 6 applicators tube test for Child-Resistant Effectiveness	48095216	Virbac All, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Child-Resistant Effectiveness	48095217	Virbae AH, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 1 applicator tube test for Senior-Use Effectiveness	48095218	Virbae Al·l, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator fube with 0.5 ml water, 6 applicators tube test for Senior-Use Effectiveness	48095219	Virbac AH, Inc	OWN	
40 CFR 157	Evaluation of the 1 ml Applicator Tube with 0.5 ml water, 36 applicators tube test for Senior-Use Effectiveness	48095220	Virbac AH, Inc	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Child-Resistant Effectiveness	48410018	Virbae All, Inc	OWN	
40 CFR 157	Evaluation of the 1ml applicator tube with 0.50 ml water, 3 applicator tube test for Scnior-Use Effectiveness	48410019	Virbac AH, Inc	OWN	
Signature		**************************************	Name and Title	•	Date
1 1.			Craig Parks		July 31,
11:61			Vice President, Research & Develop	ment	2012

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TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Virbac Animal Health, Inc. (EPA Company Number 2382) P.O. Box 162059 Fort Worth, TX 76161

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

This submission is an application to register an end use product named $EFF1T1X^{TM}$ Plus Topical Solution for Dogs.

SUBMITTAL DATE:

August 2, 2012

Volume	Study Name (Lab Reference Number)	MRID
TRANSM17	TTAL DOCUMENT	48896300
1	Product Specific Chemistry For Effitix TM Plus Topical Solution for Dogs	48896301
2	Quantification of the Active Ingredients Fipronil, Permethrin and Pyriproxifen in Five Batches by Validated Methods	48896302
3	Determination of the physic-Chemical Property Appearance (Color, Physical State, and Odor) (D42327)	48896303
4	Determination of Oxidation/reduction: Chemnical Incompatability (D42305)	48896304
5	Determination of the Physico-Chemical Property "Flash Point" (D42316)	48896305
6	Determination of the Physico-Chemical Property Viscosity (D42272)	48896306
7	Determination of the Physico-Chemical Property pH (D42294)	48896307
8	Determination of the Physico-Chemical Property Relative Density (D42283)	48896308
9	Acute oral toxicity (D42171)	` 48896309
10	Acute dermal toxicity (D42182)	` 48896310
11	Primary eye irritation (D42193)	48896311
12	Primary dermal irritation (D42202)	48896312
13	Dermal sensitization (D42215)	48896313
14	Summary of Efficacy Data For Effitix TM Plus Topical Solution for Dogs	48896314
15	Summary of Companion Animal Safety Data For Effitix TM Plus Topical Solution for Dogs	48896315

Commercial/financial information may be entitled to confidential treatment

Invoice	Date	Invoice	Description	Gross Amount	Discount	Invoice Amount
071312US	13-JUL-12	REGISTR	ATION FEE EFI	4,807.00	0.00	4,807.00
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		TOTALS		4,807.00	0.00	4,807.00
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